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Van Bladel et al.

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(54) **CARDIAC TISSUE PENETRATING DEVICES, METHODS, AND SYSTEMS FOR TREATMENT OF CONGESTIVE HEART FAILURE AND OTHER CONDITIONS**

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(73) Assignee: **BioVentrix, Inc.**, San Ramon, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 527 days.

This patent is subject to a terminal disclaimer.

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(51) **Int. Cl.**
A61B 5/0215 (2006.01)
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(Continued)

(52) **U.S. Cl.**
CPC ***A61B 5/0215*** (2013.01); ***A61B 1/0058*** (2013.01); ***A61B 5/065*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC .. A61F 2/2478; A61F 2/2487; A61F 17/0487; A61F 2002/249;
(Continued)

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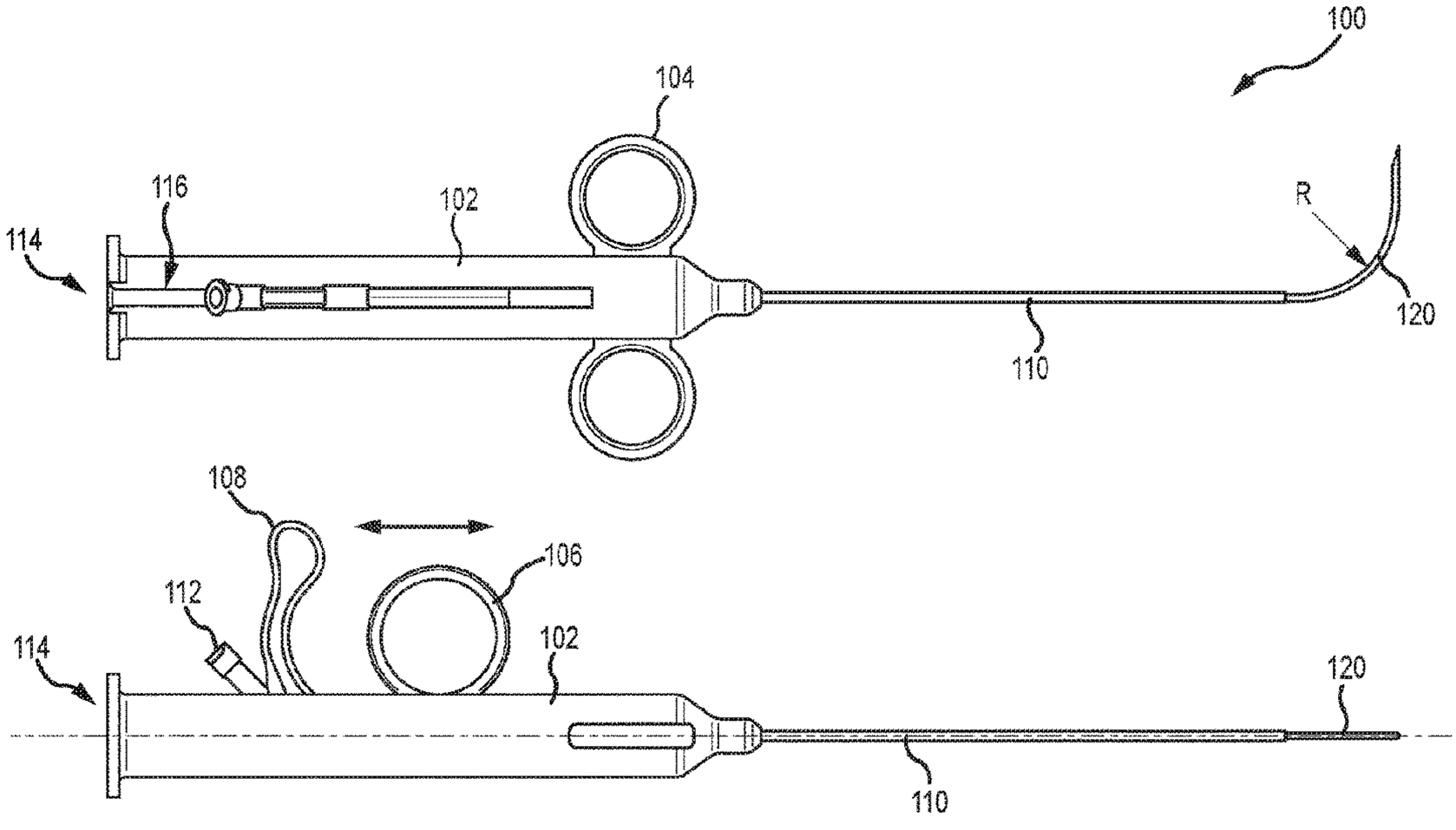
(74) *Attorney, Agent, or Firm* — Nixon & Vanderhye P.C.

(57) **ABSTRACT**

According to one embodiment, a tissue penetrating device includes an elongate shaft having a proximal end, a distal end, and a lumen extending there between. A first needle is disposed within the lumen of the elongate shaft and is extendable therefrom between a first configuration and a second configuration. In the first configuration, the first needle is disposed within the elongate shaft's lumen and is substantially aligned with an axis of the lumen. In the second configuration, the first needle extends distally of the elongate shaft's distal end and bends away from the lumen's axis. A second needle is disposed within a lumen of the first needle and is extendable therefrom when the first needle is positioned in the first configuration and when the first needle is positioned in the second configuration. The second needle may be extended from the first needle to penetrate tissue of a patient.

6 Claims, 18 Drawing Sheets



Related U.S. Application Data

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(51) **Int. Cl.**

A61B 17/04	(2006.01)
A61B 1/005	(2006.01)
A61B 5/06	(2006.01)
A61B 17/00	(2006.01)
A61B 17/06	(2006.01)

(52) **U.S. Cl.**

CPC ***A61F 2/2487*** (2013.01); *A61B 17/0487* (2013.01); *A61B 2017/00243* (2013.01); *A61B 2017/00247* (2013.01); *A61B 2017/0409* (2013.01); *A61B 2017/0417* (2013.01); *A61B 2017/06052* (2013.01); *A61F 2002/249* (2013.01)

(58) **Field of Classification Search**

CPC .. A61B 2017/00243; A61B 2017/0409; A61B 17/3478

See application file for complete search history.

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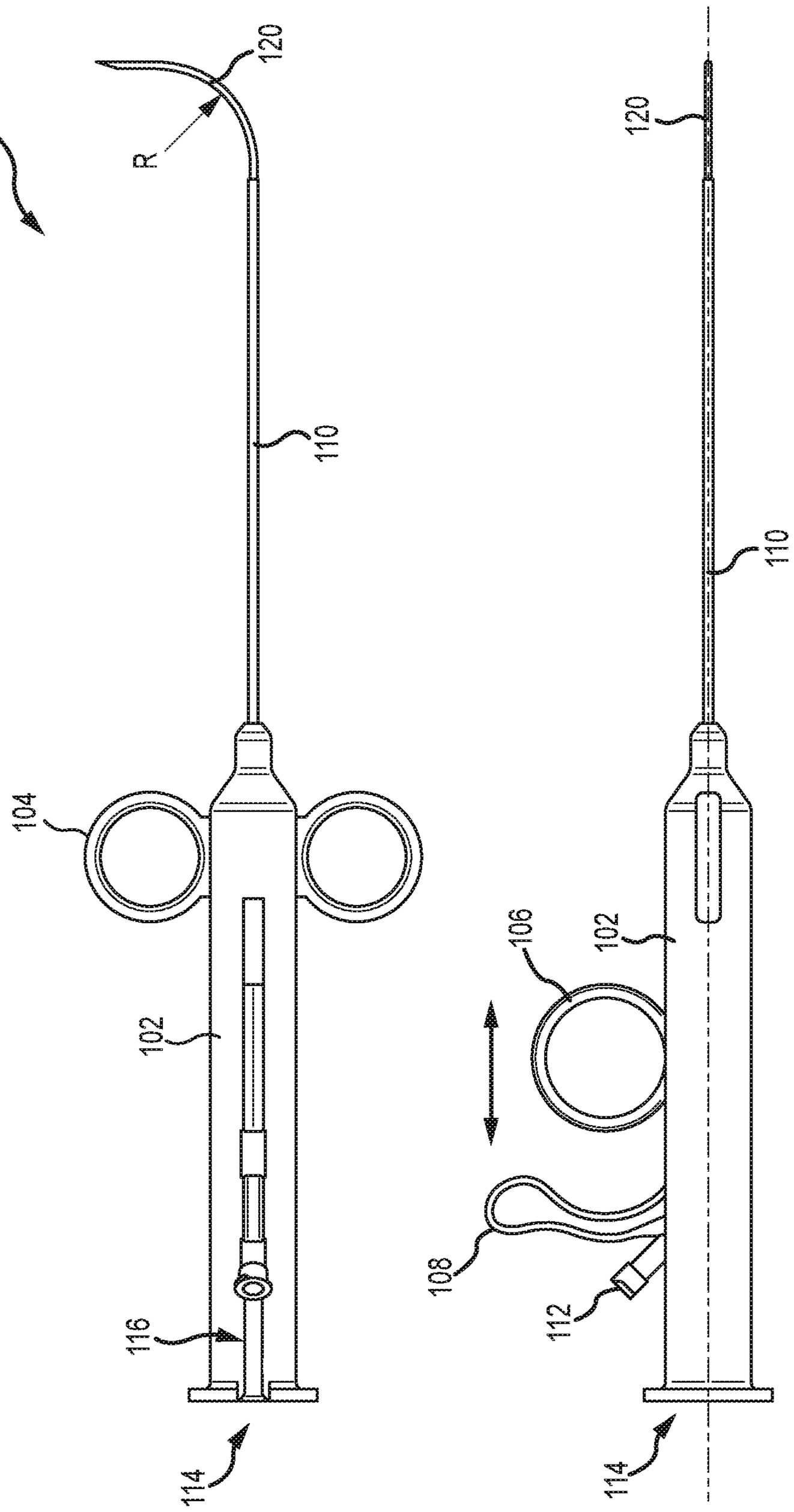


FIG. 1

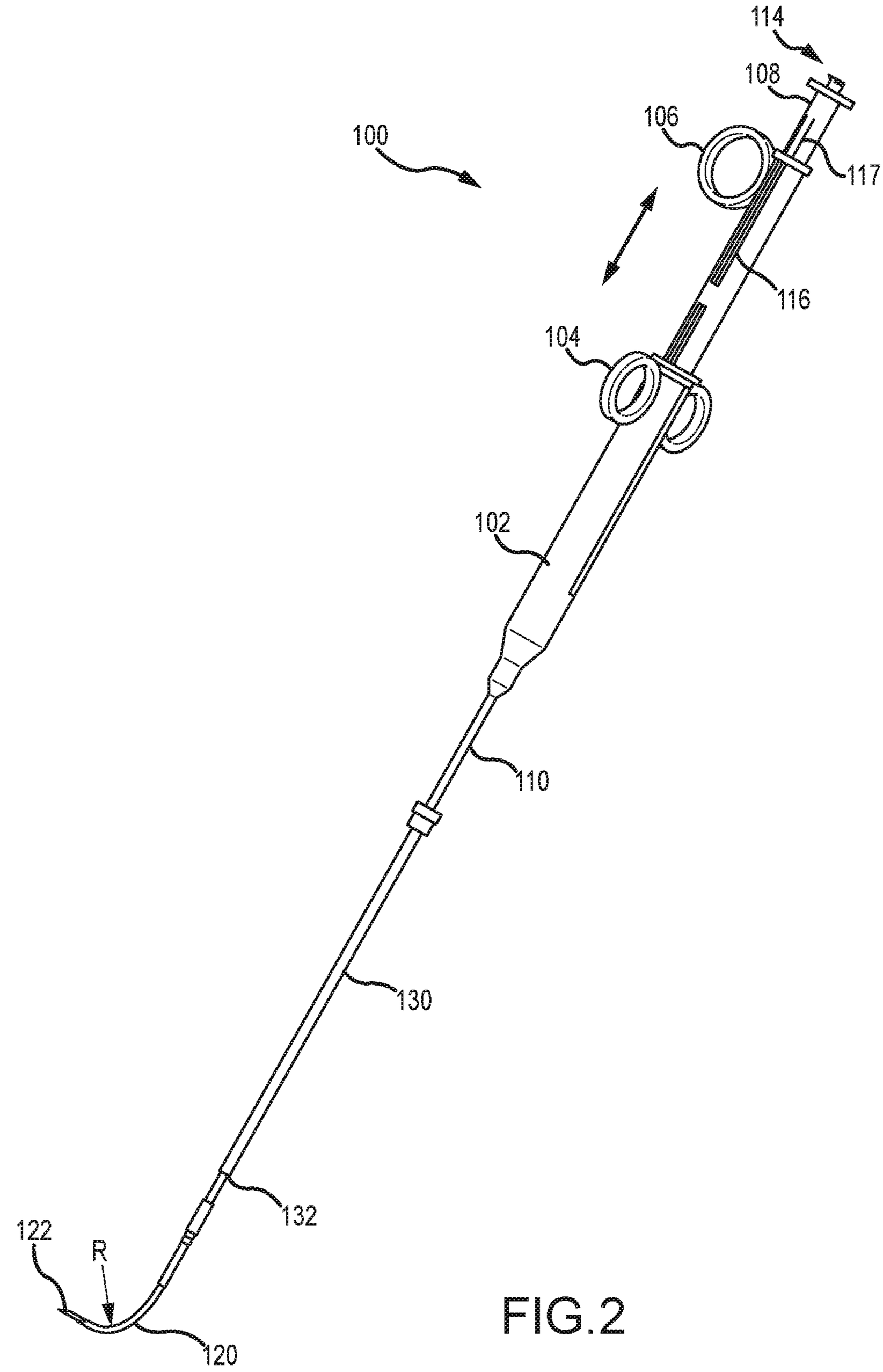


FIG.2

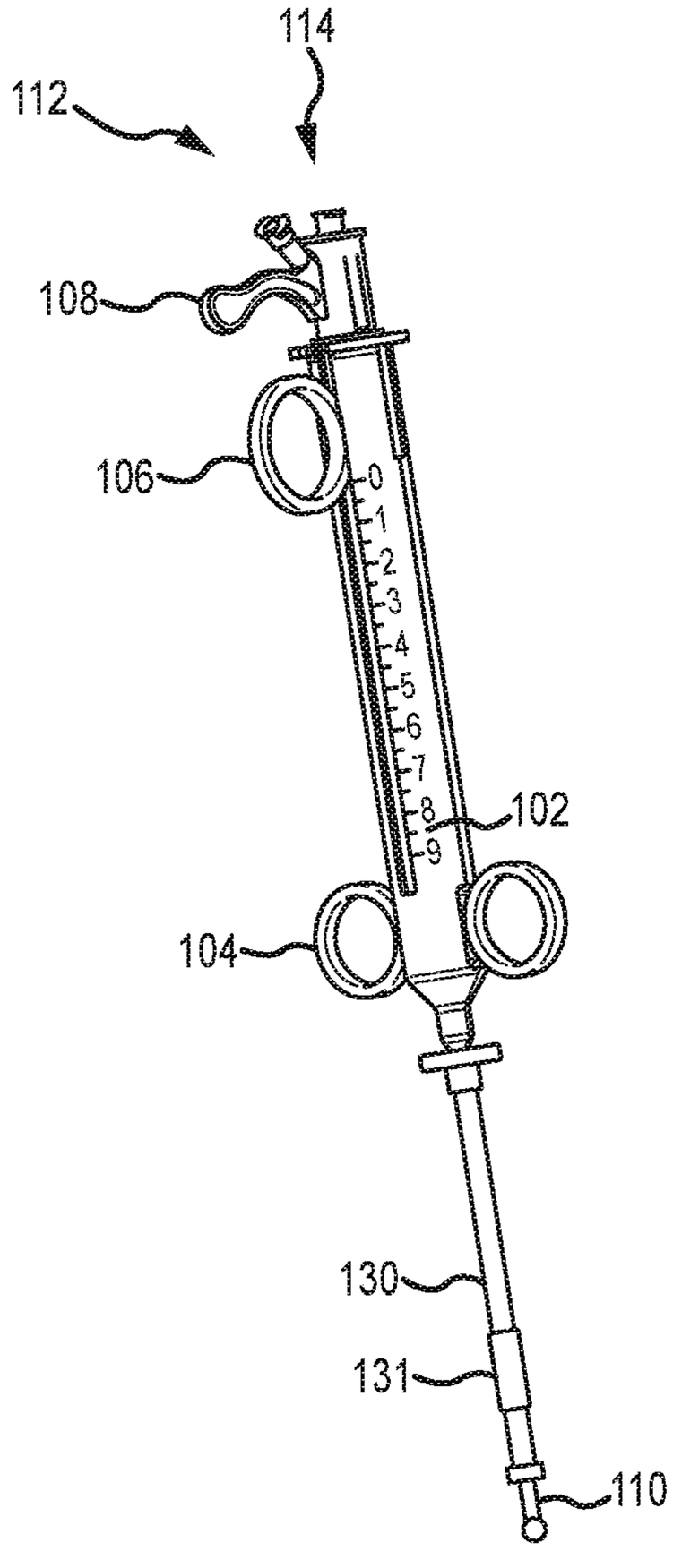


FIG.3A

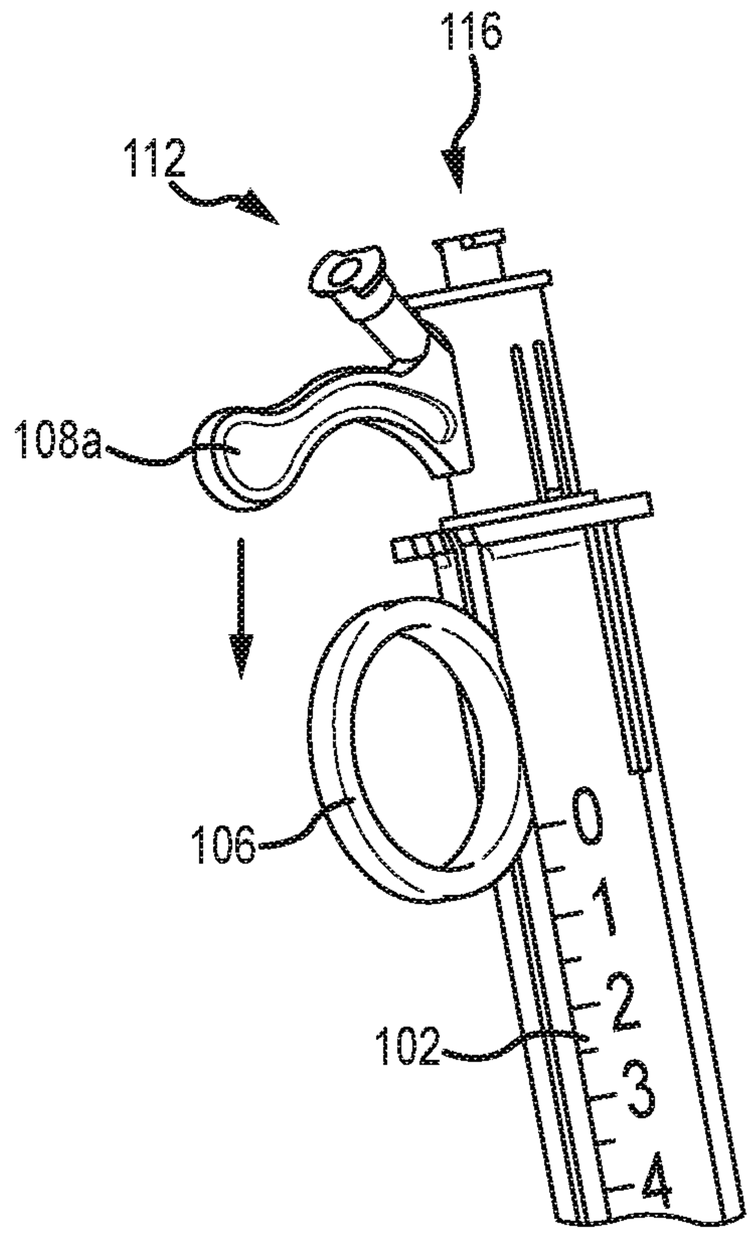


FIG.3B

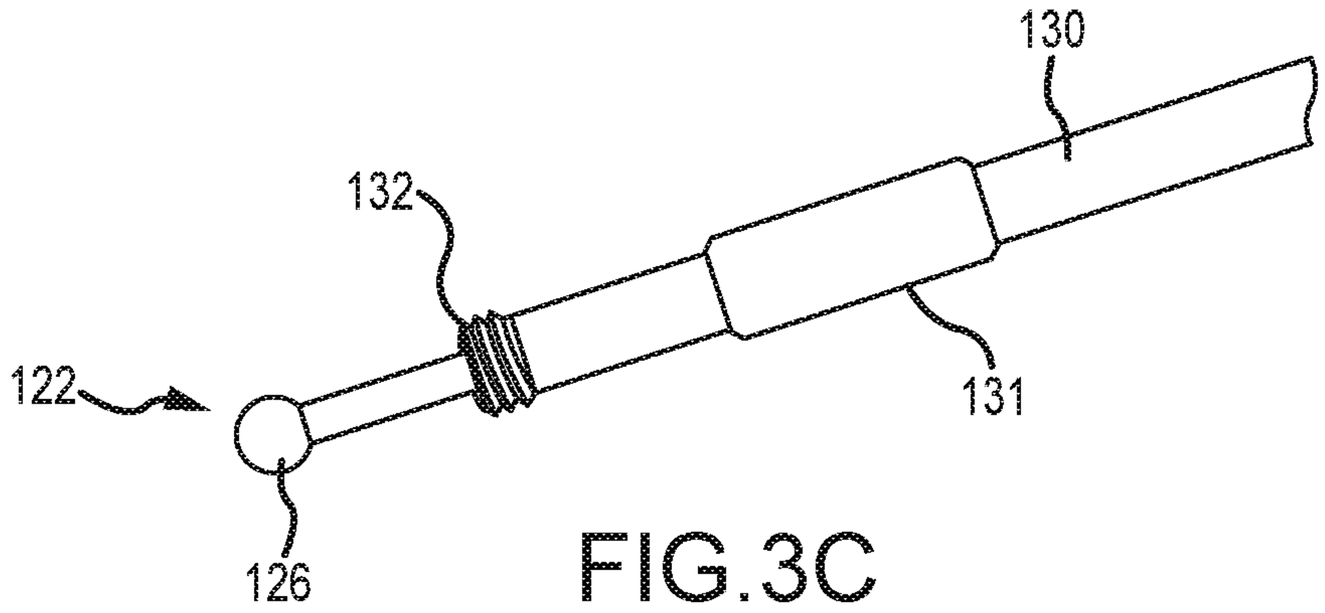


FIG.3C

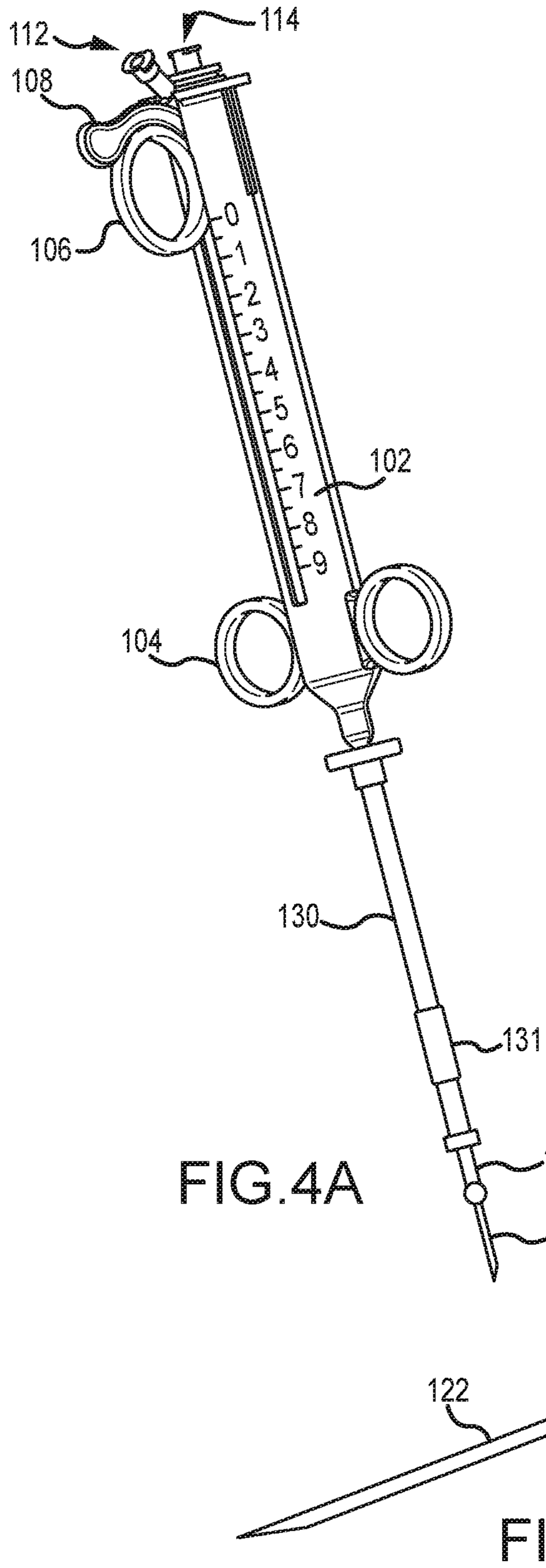


FIG.4A

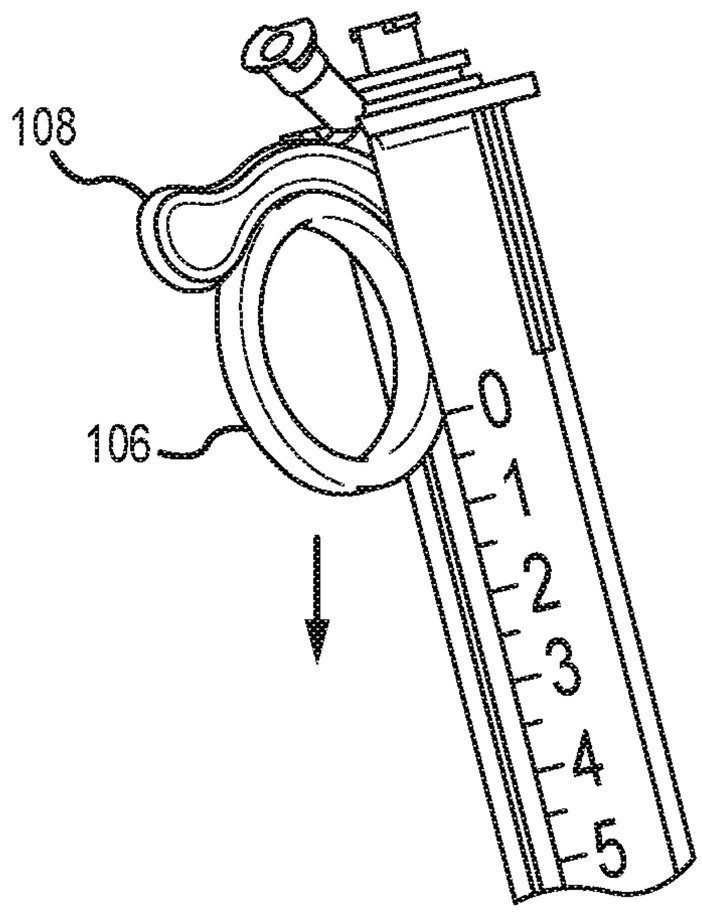


FIG.4B

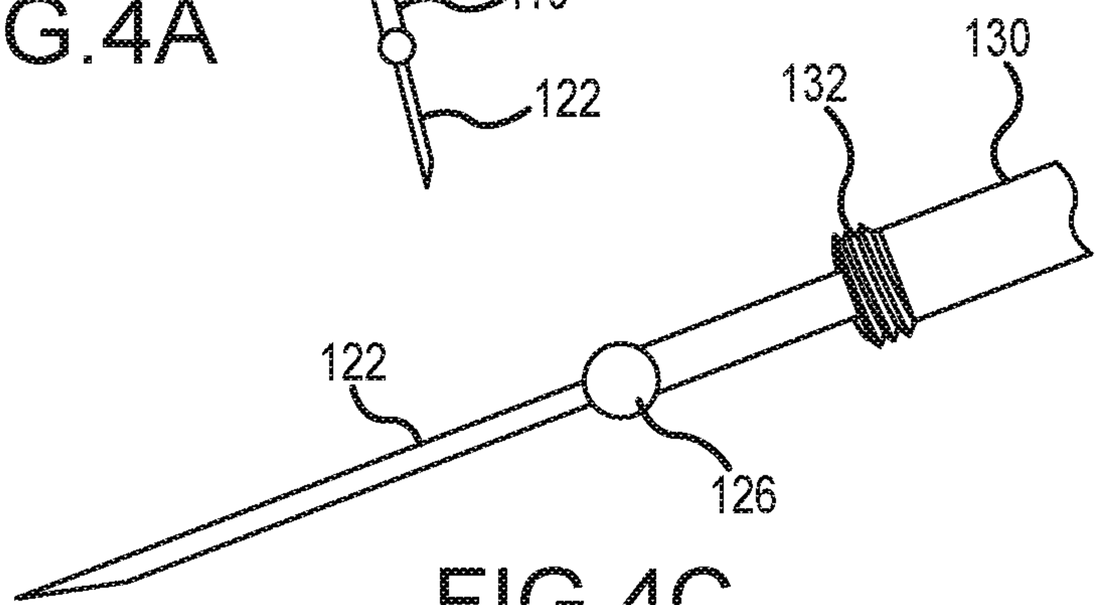


FIG.4C

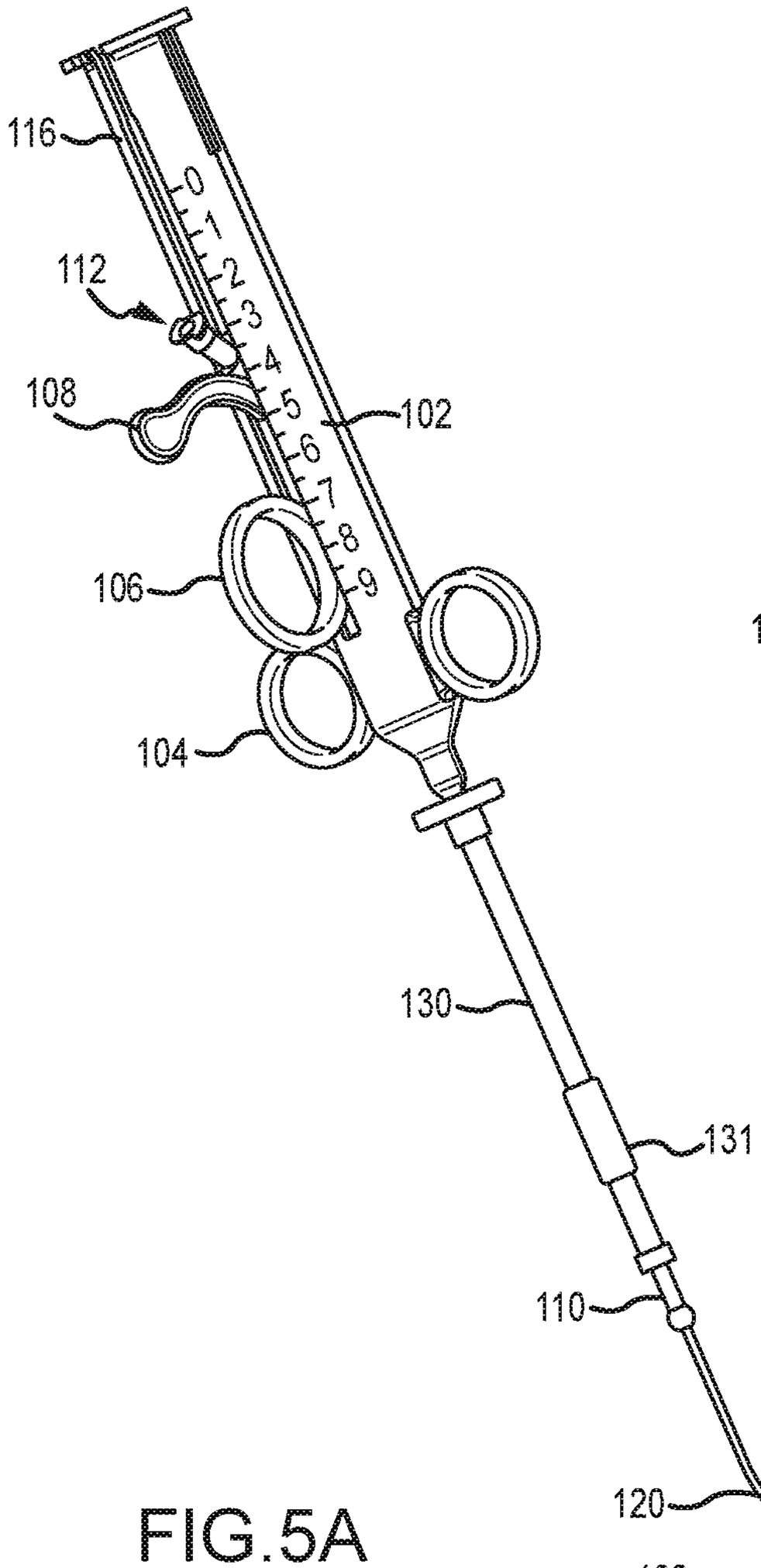


FIG.5A

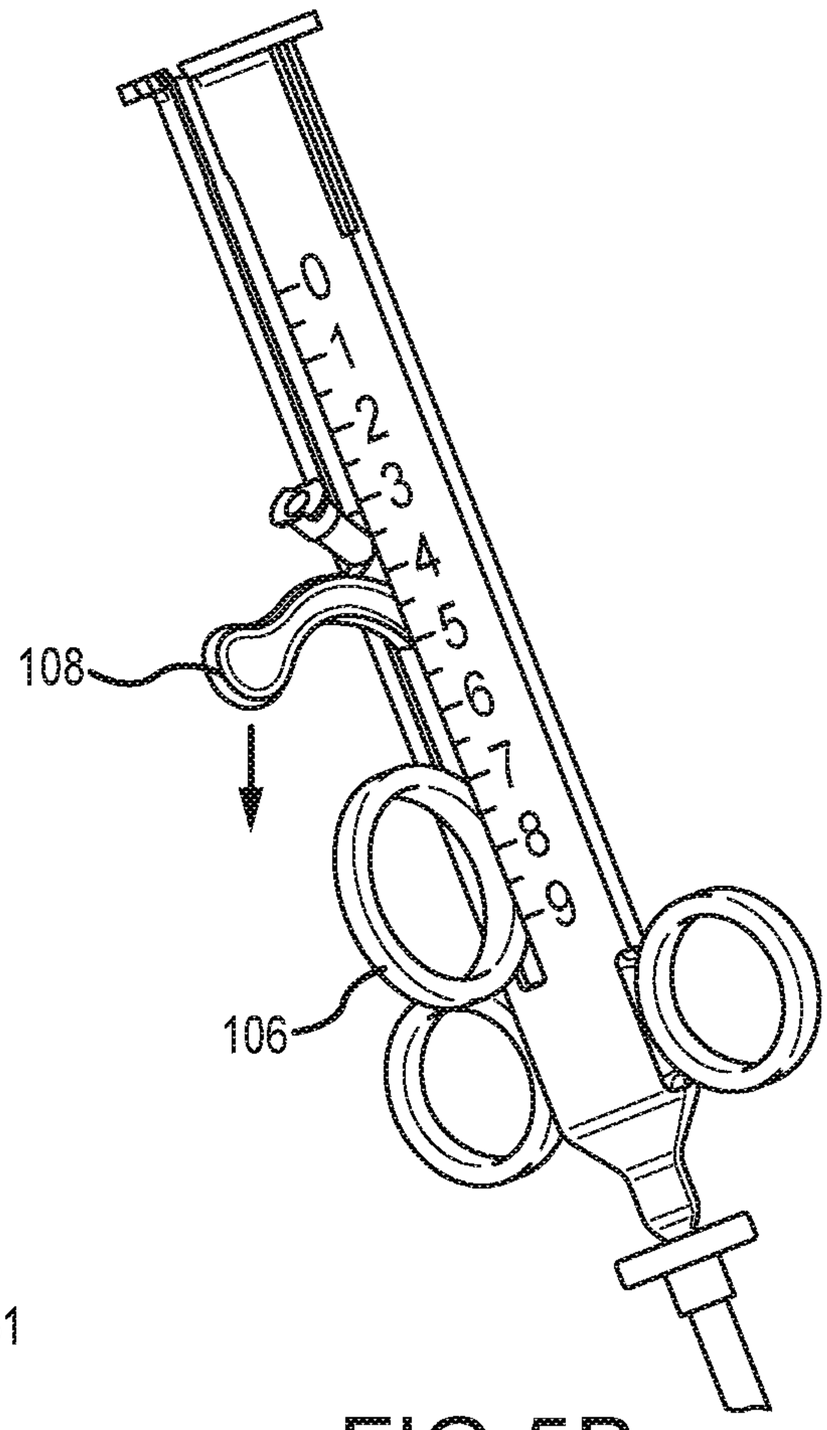


FIG.5B

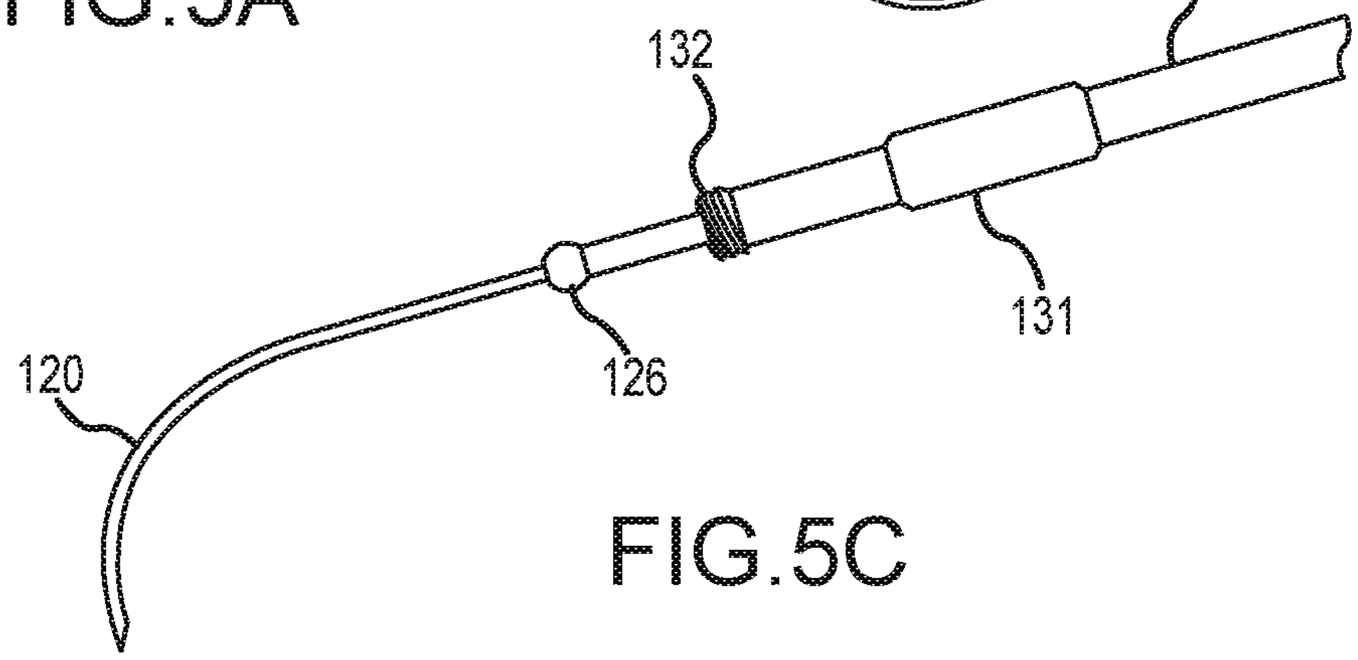


FIG.5C

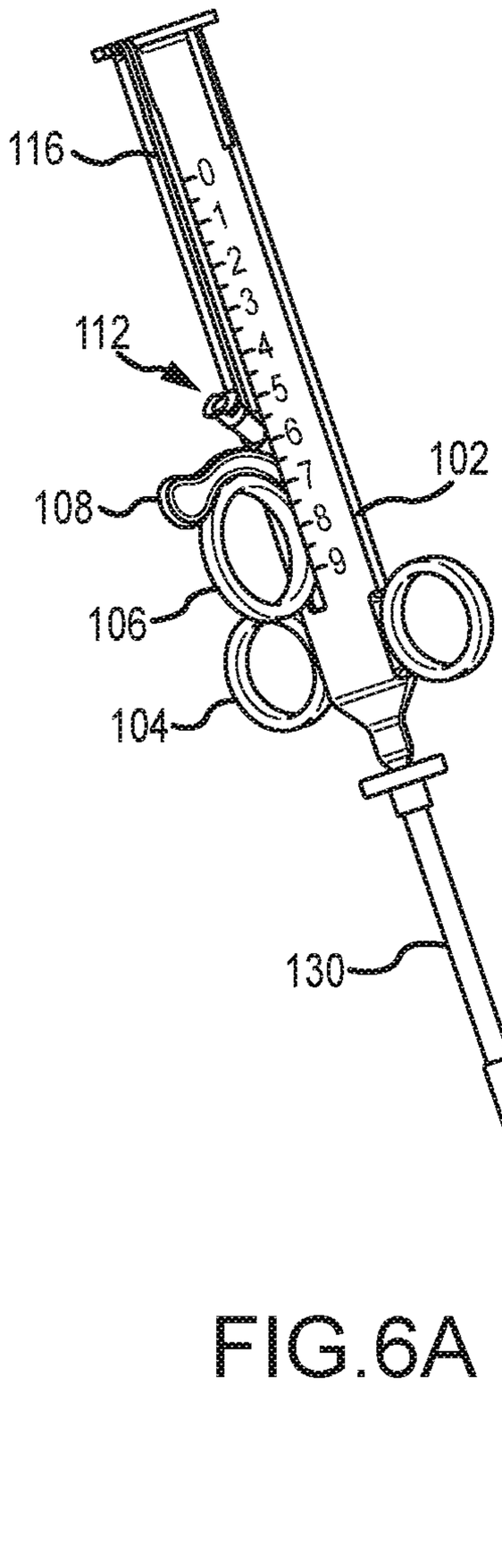


FIG.6A

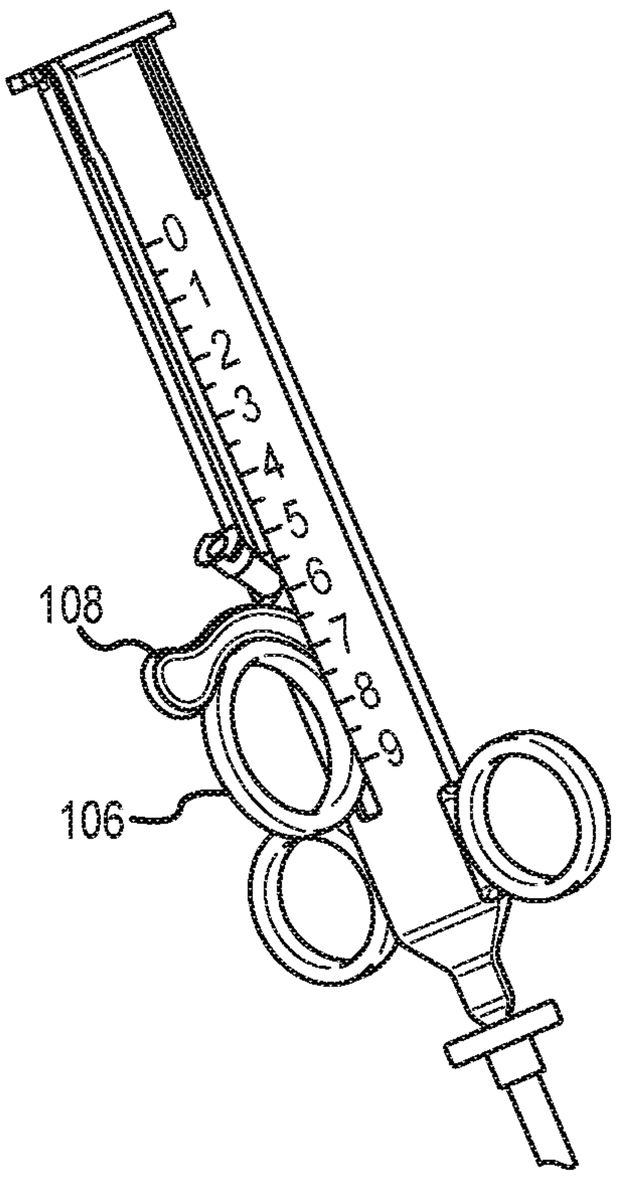


FIG.6B

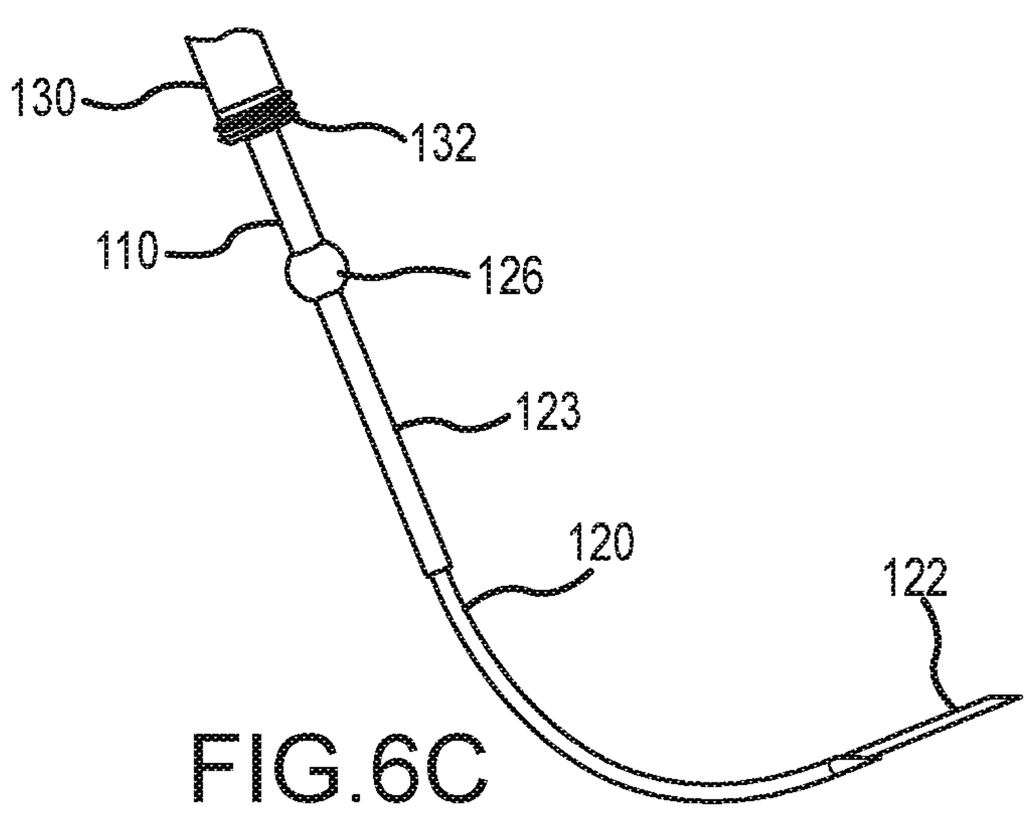


FIG.6C

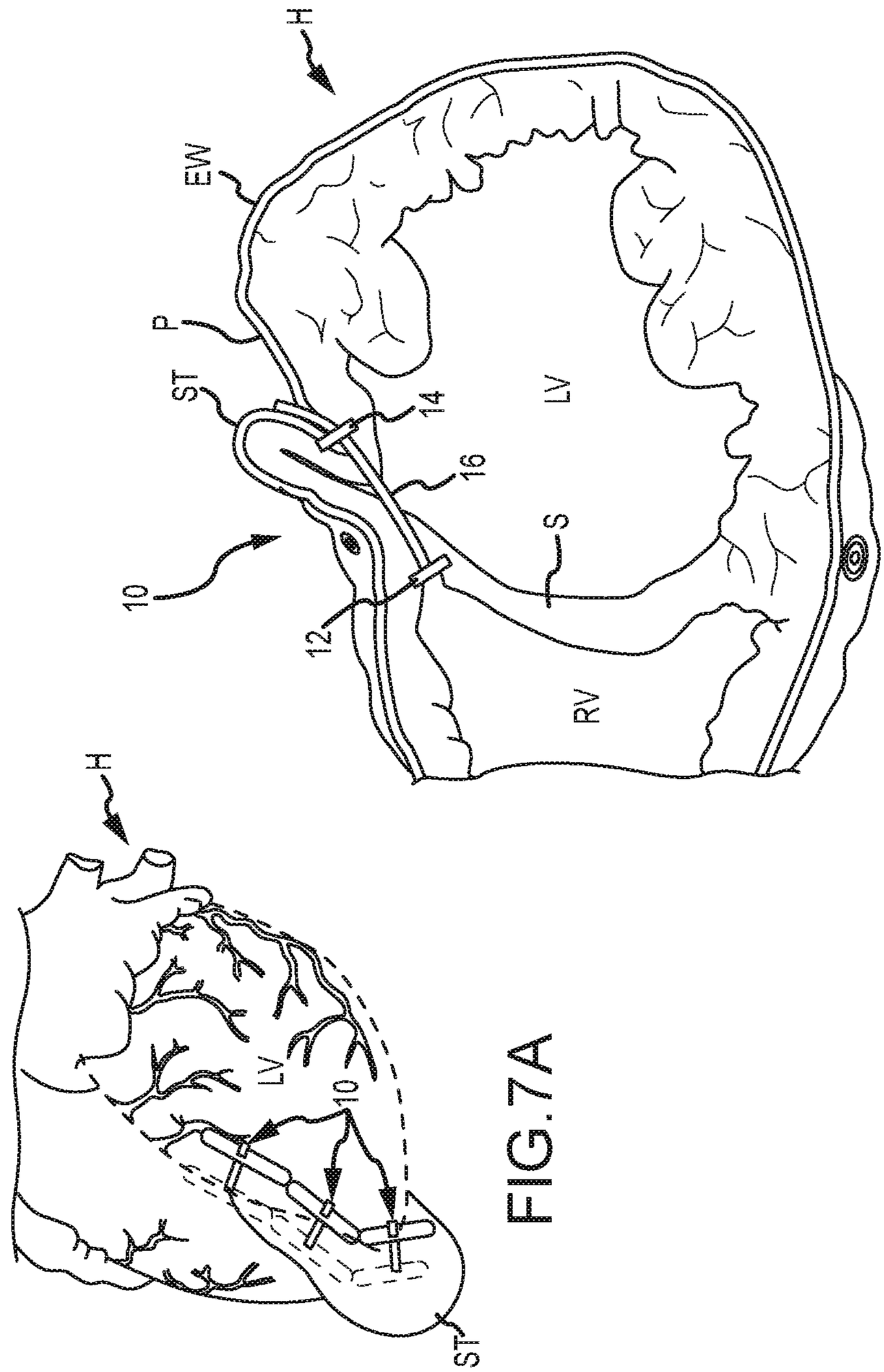


FIG.7B

FIG.7A

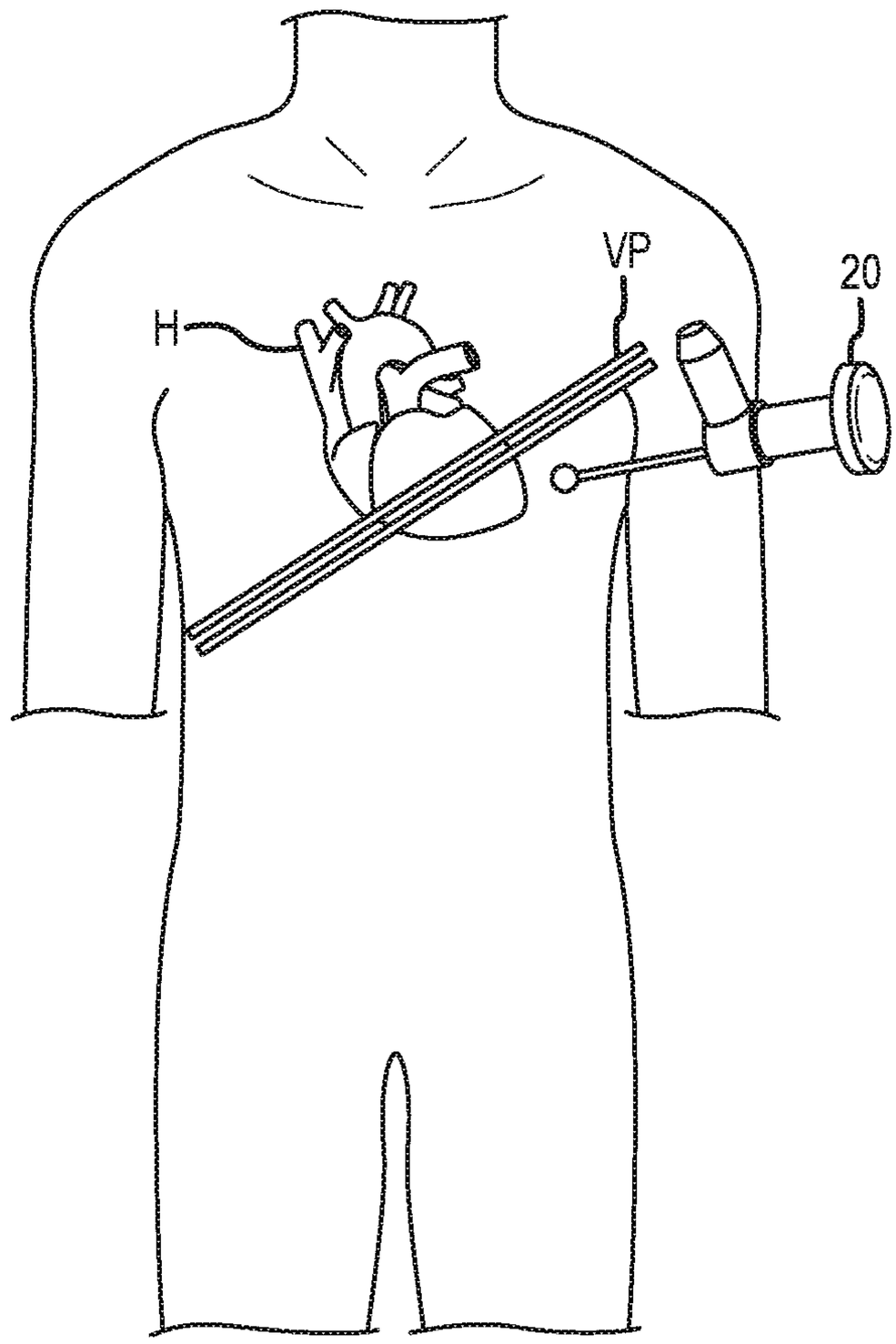


FIG.7C

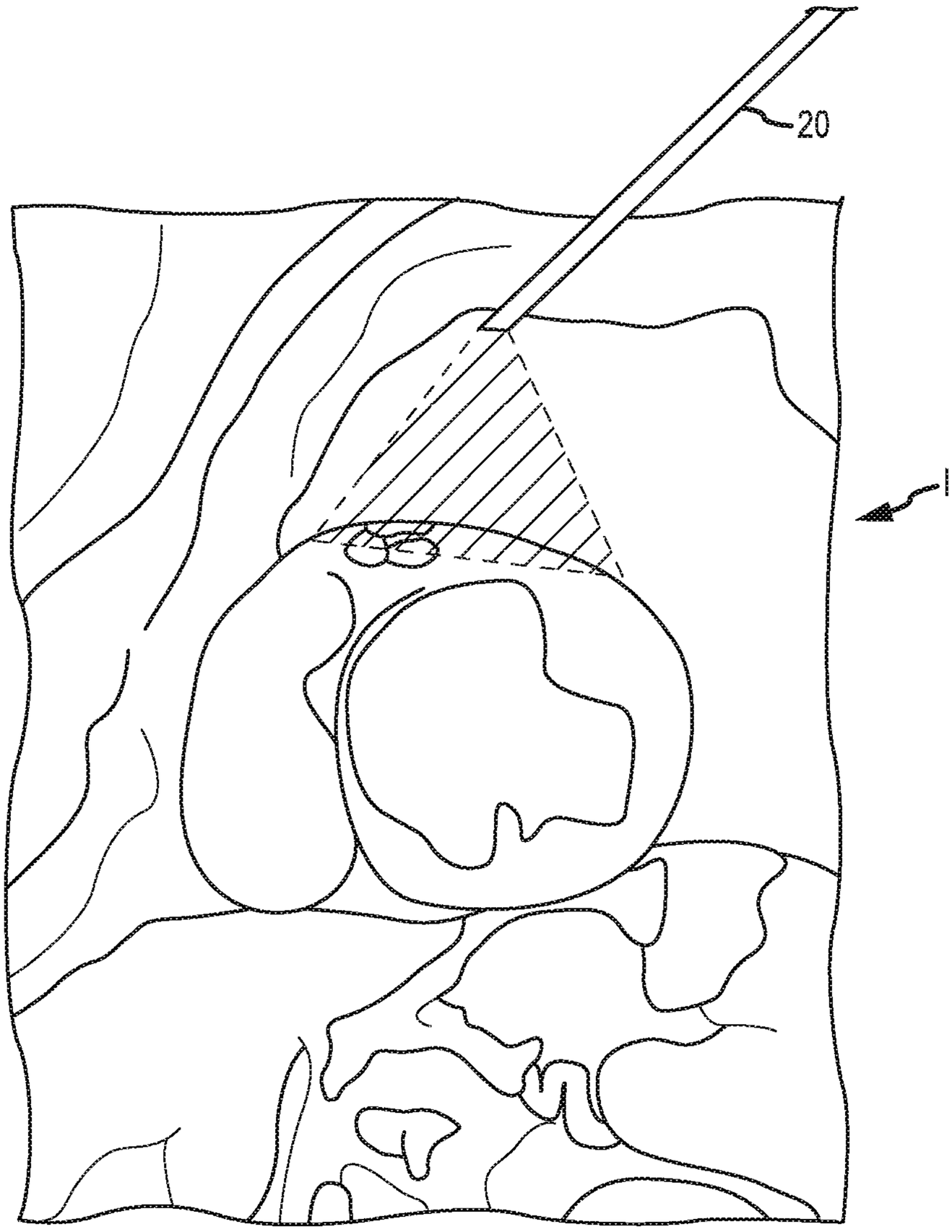
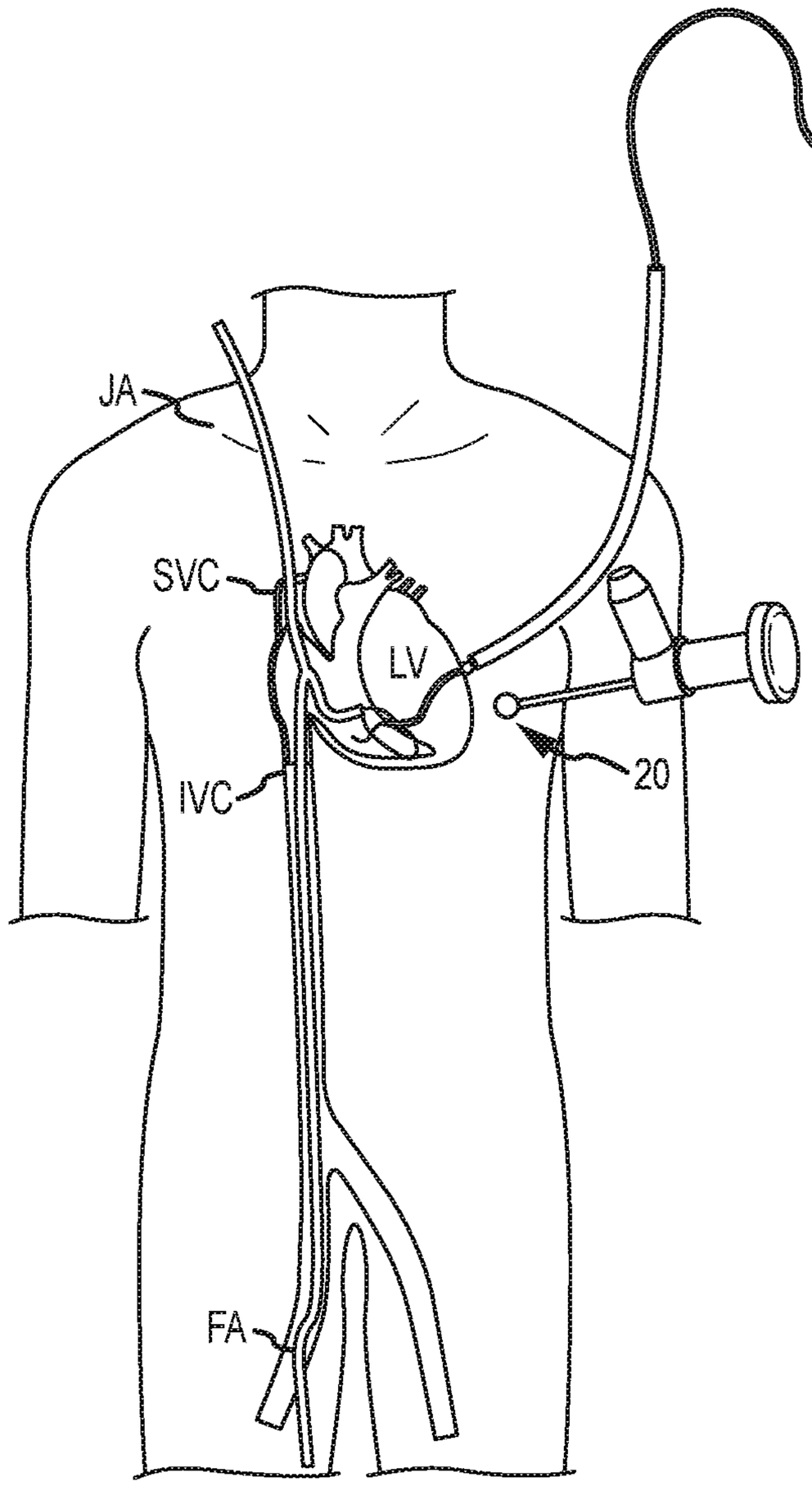


FIG.7D



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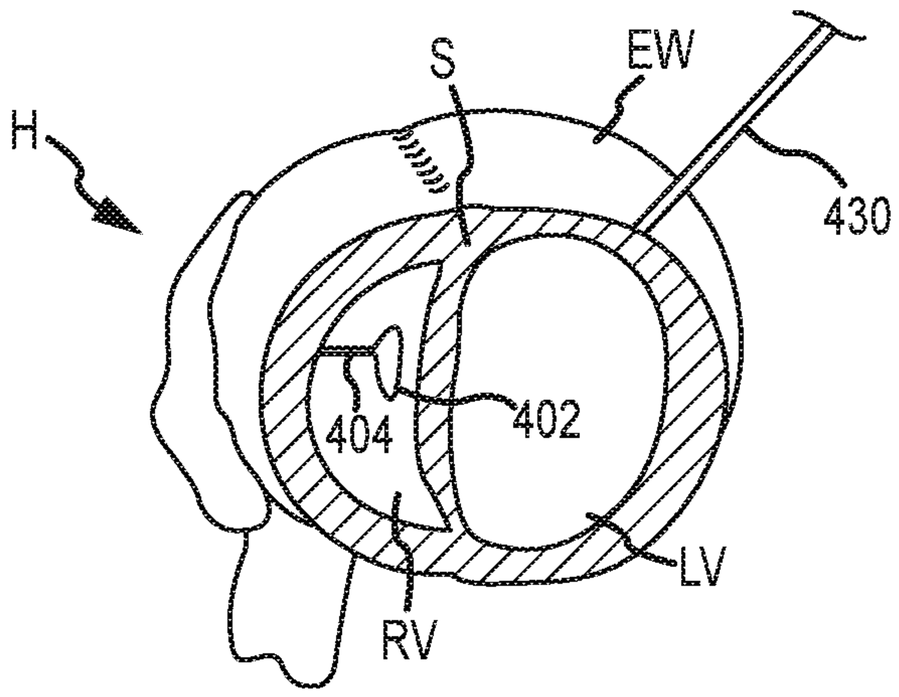


FIG.8A

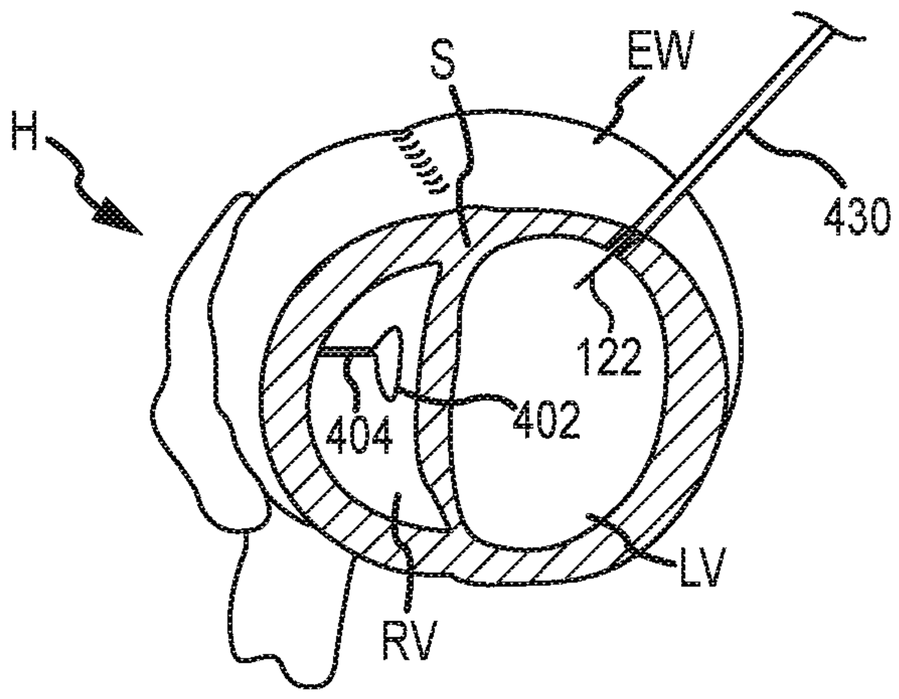
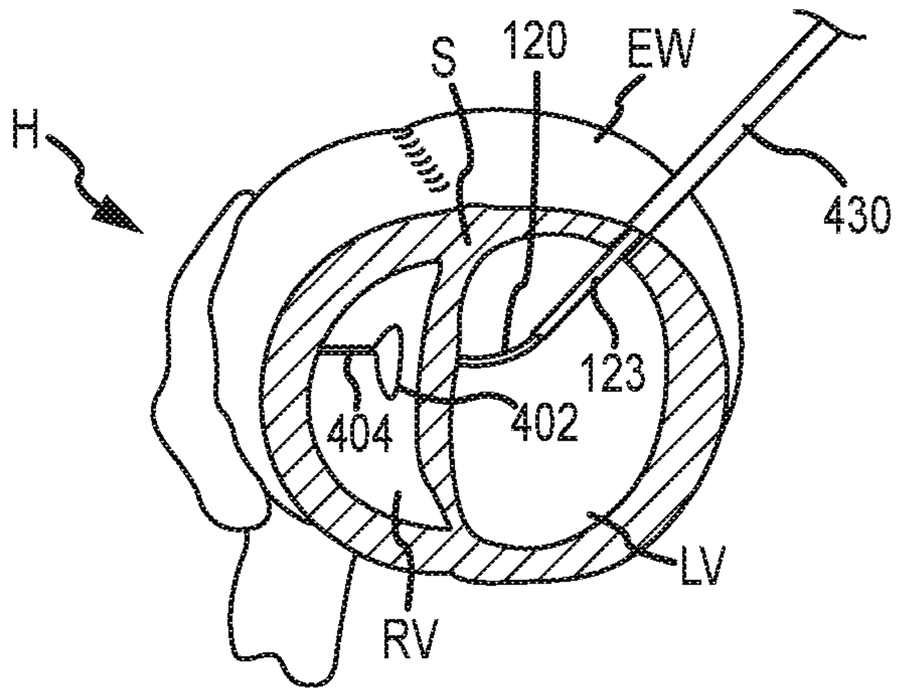


FIG.8B



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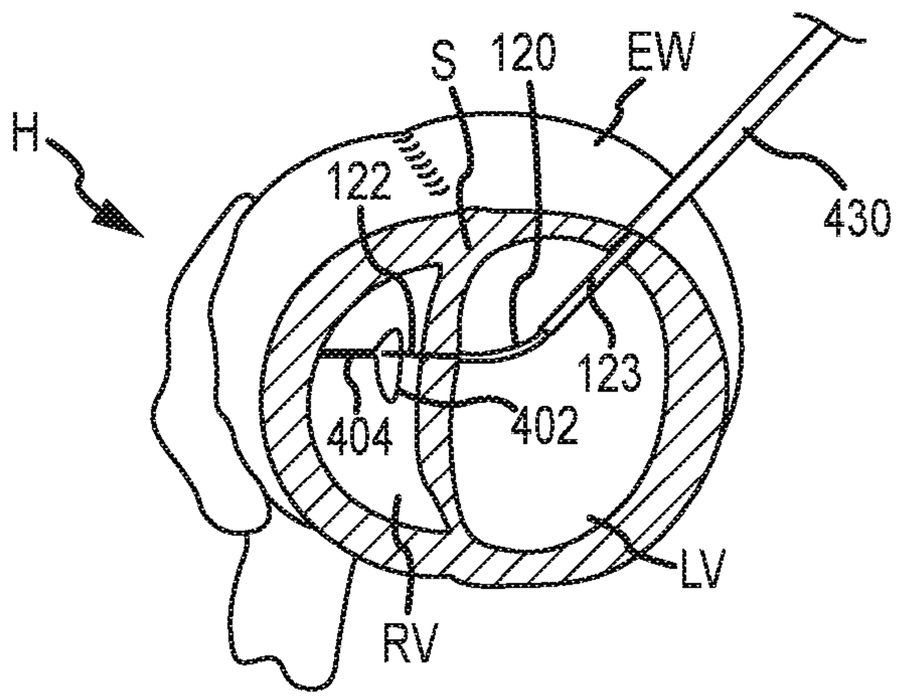

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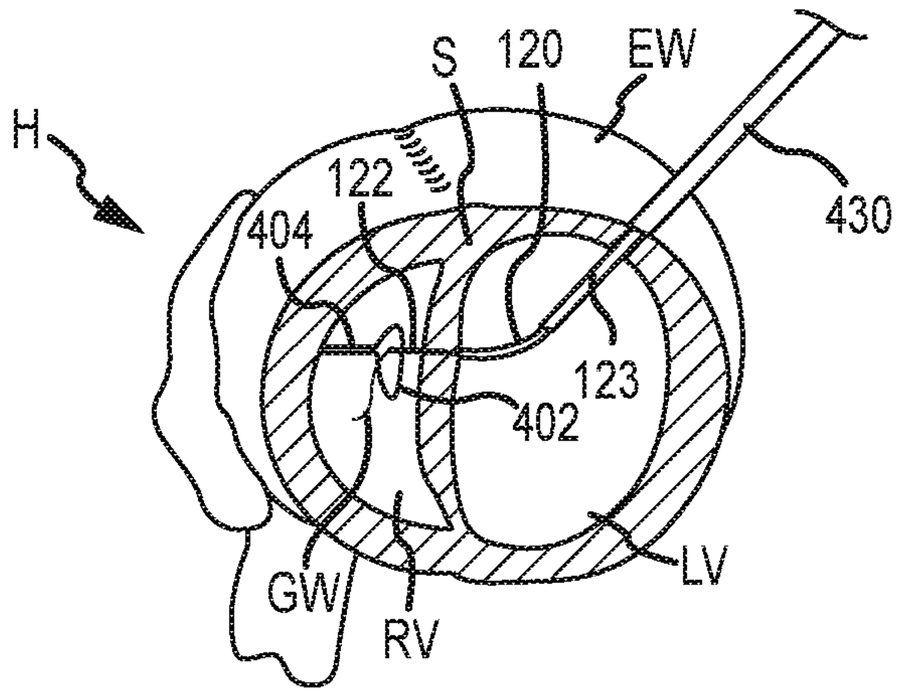

FIG.8E

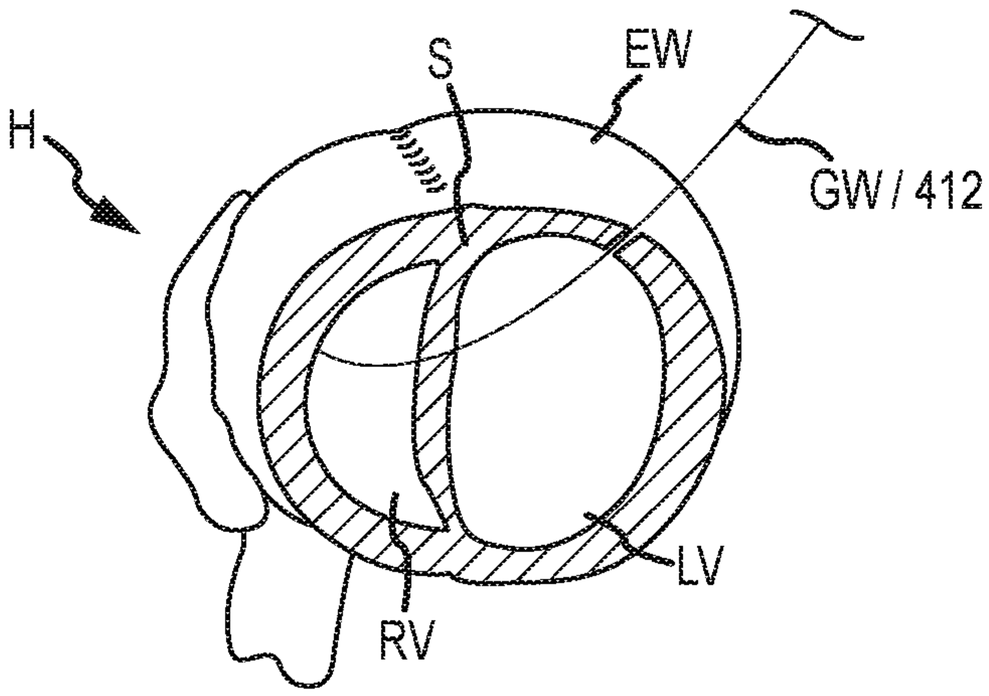

FIG.8F

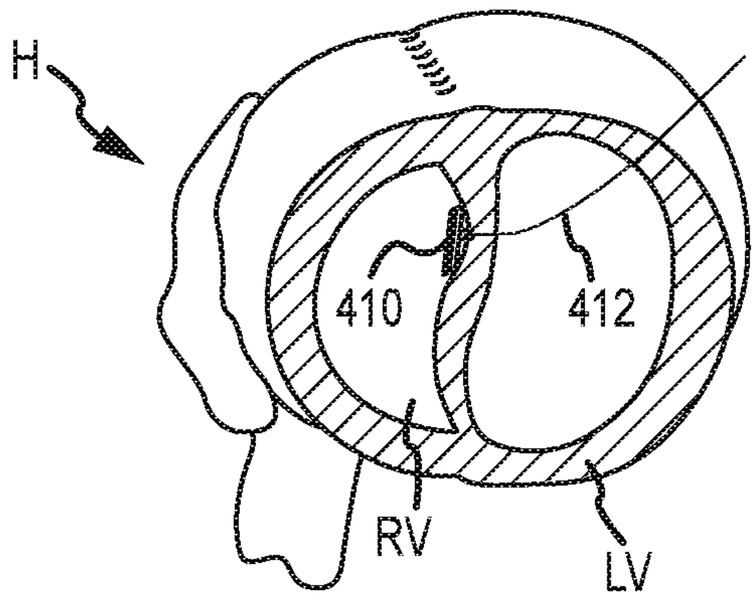

FIG.8G

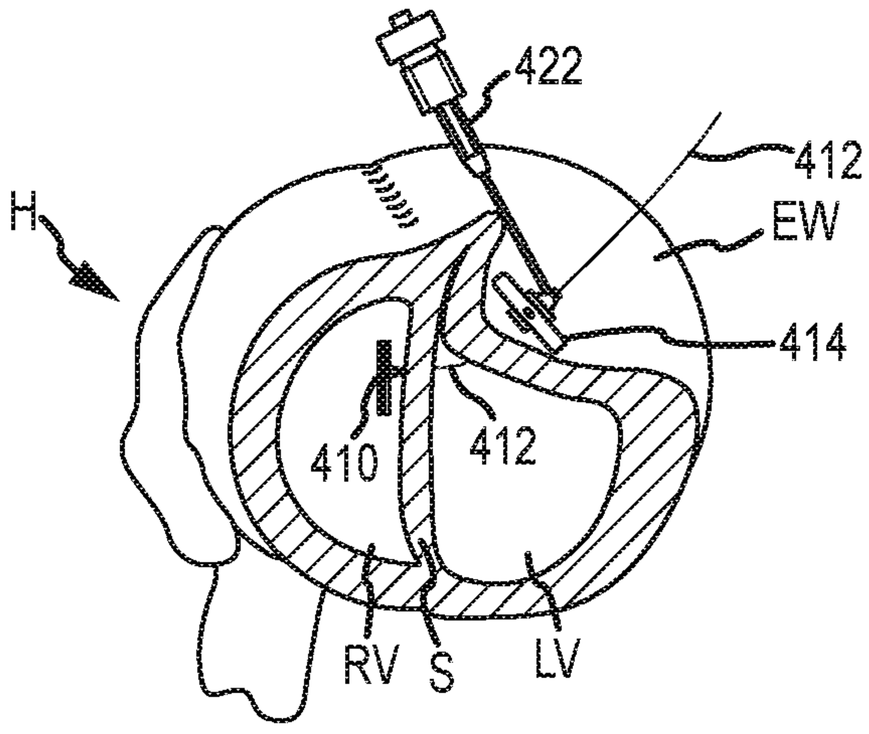

FIG.8H

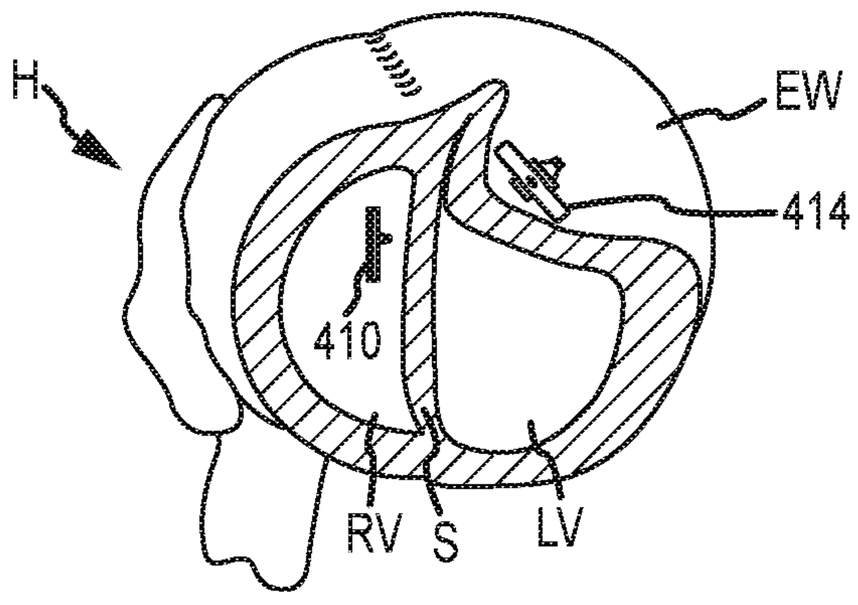

FIG.8I

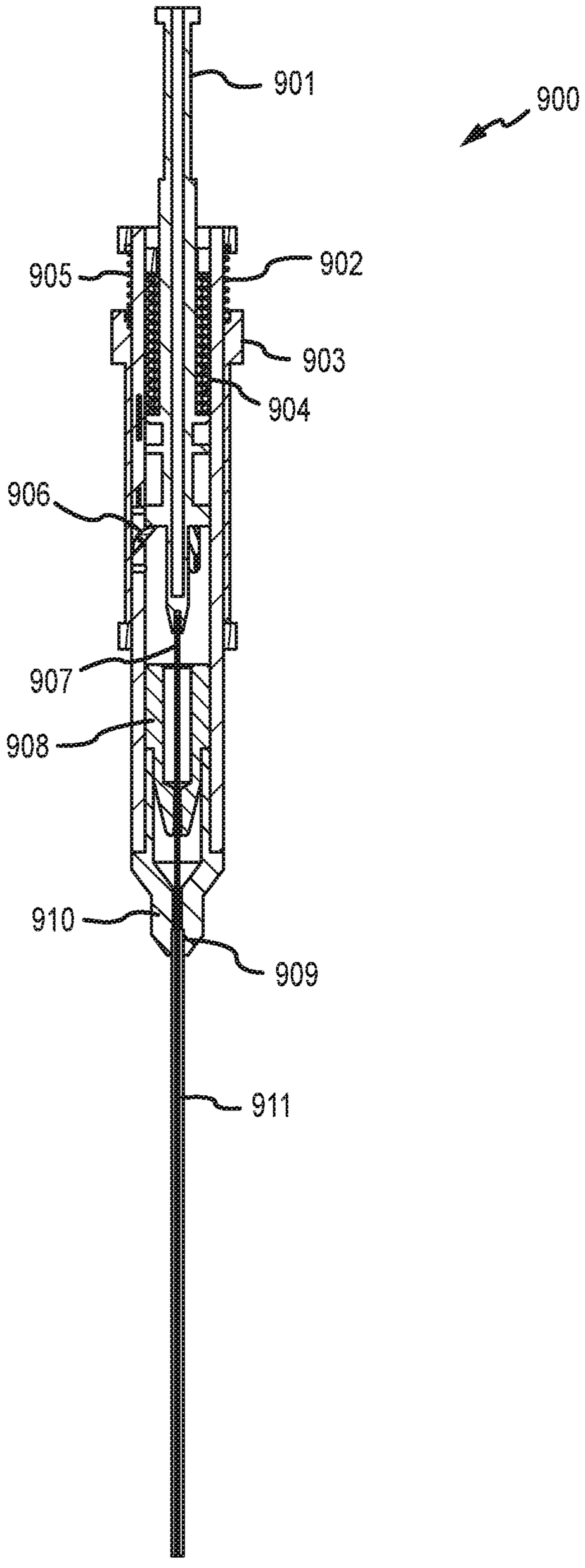

FIG.9A

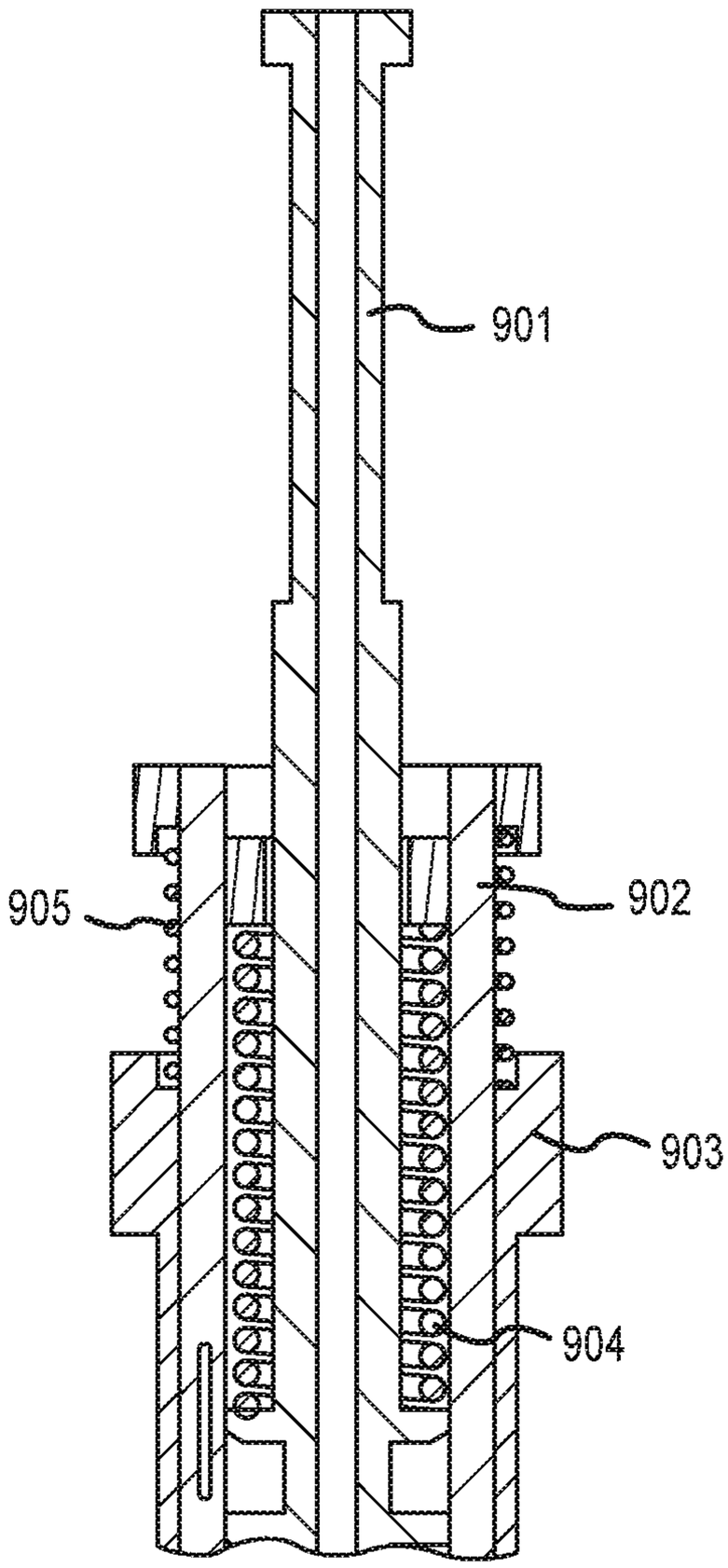

FIG.9B

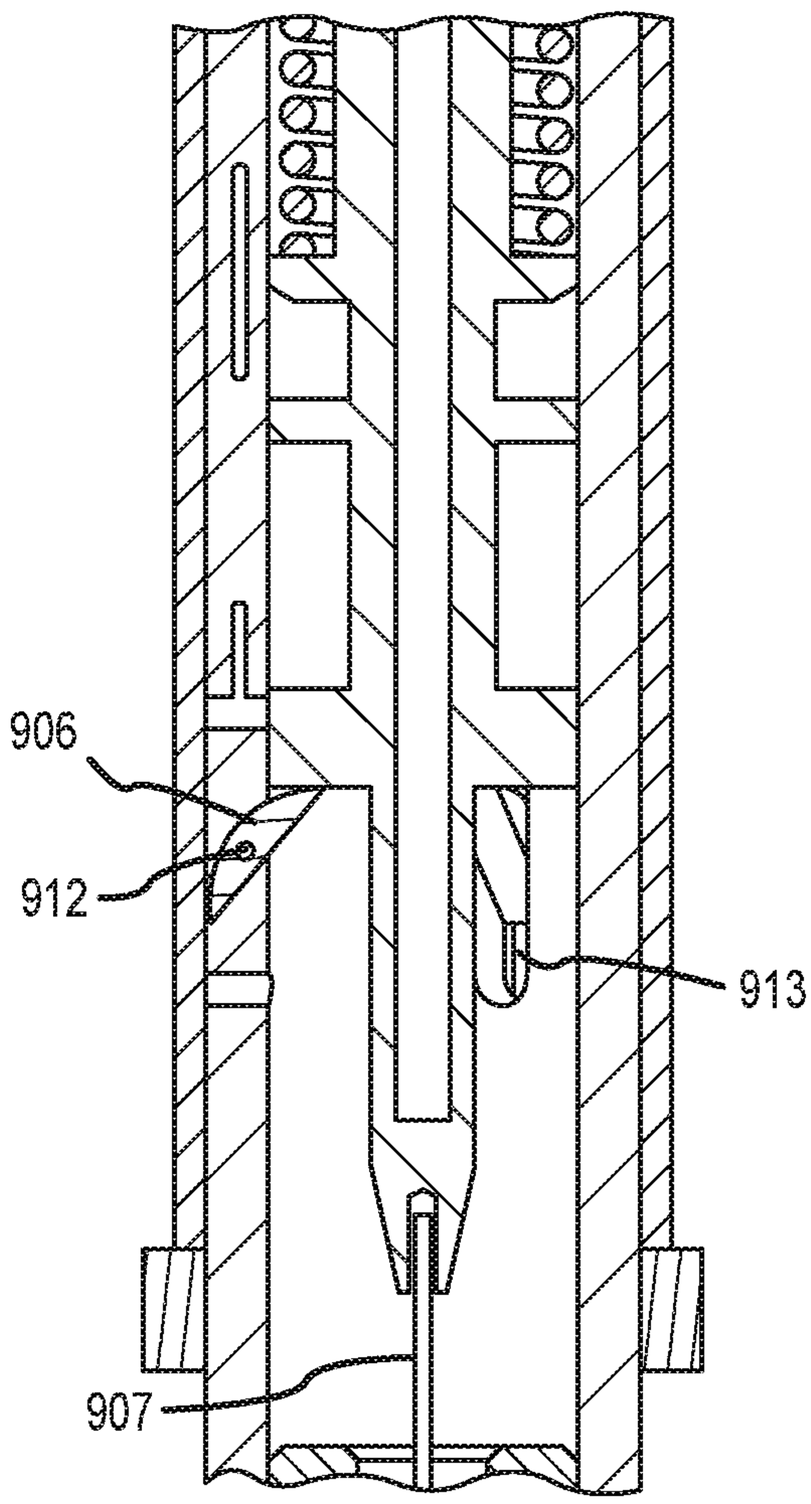

FIG.9C

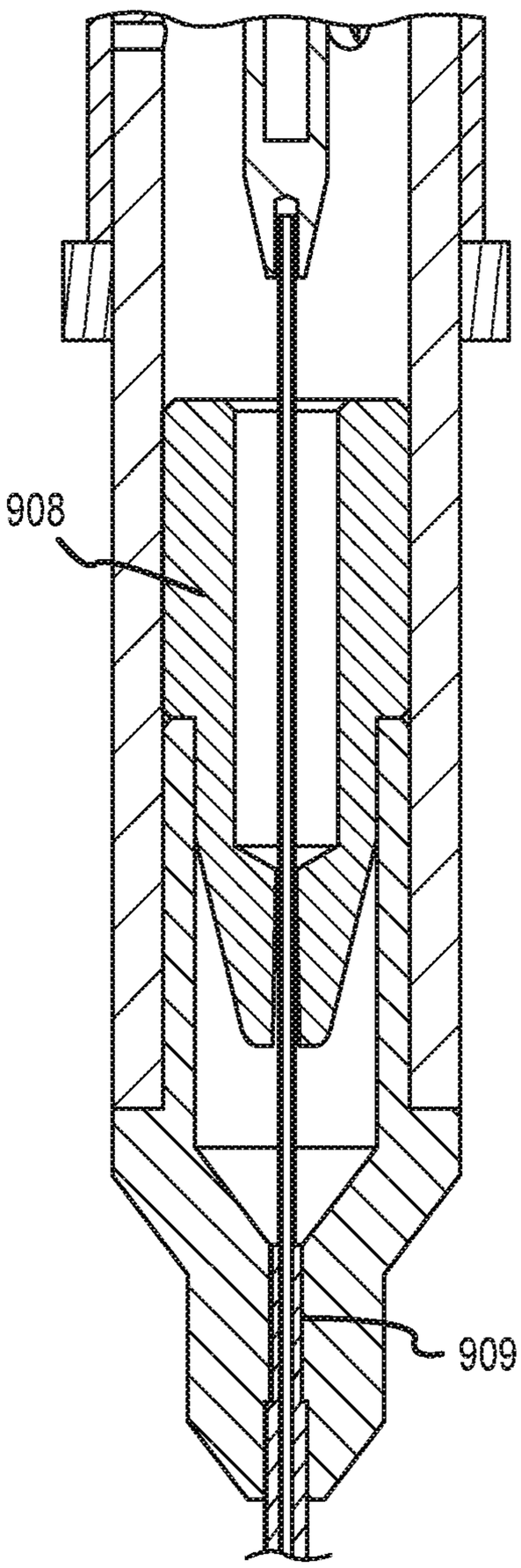

FIG.9D

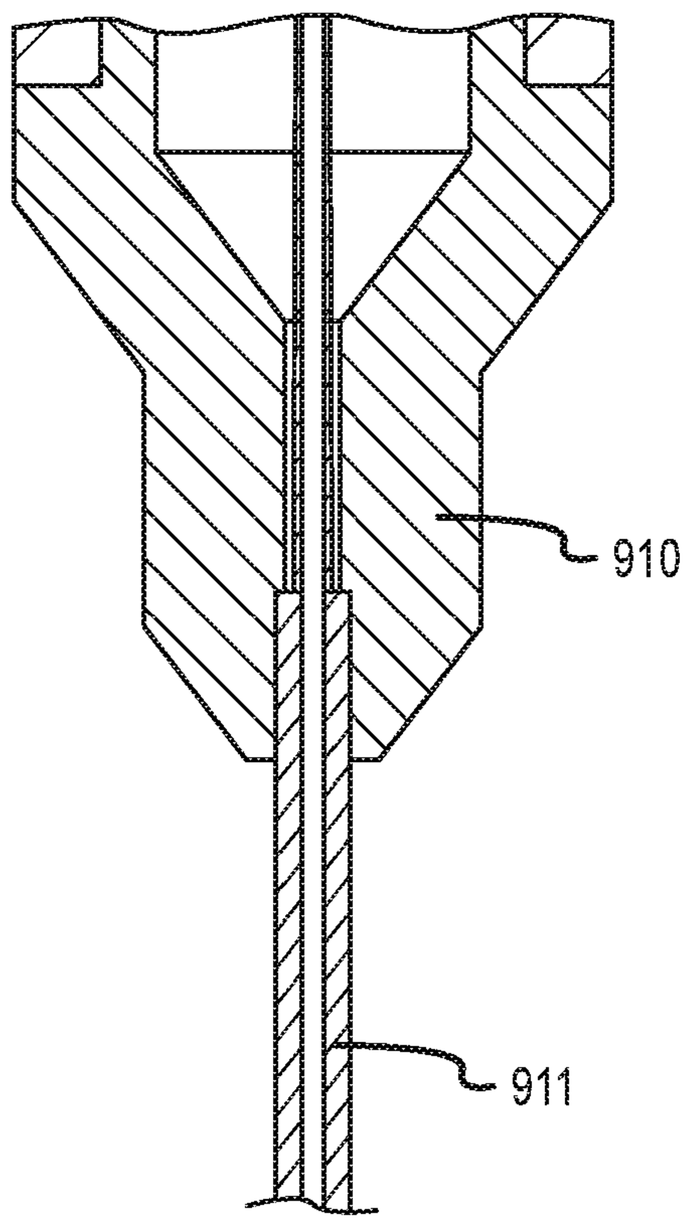

FIG.9E

CARDIAC TISSUE PENETRATING DEVICES, METHODS, AND SYSTEMS FOR TREATMENT OF CONGESTIVE HEART FAILURE AND OTHER CONDITIONS

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 14/282,849 entitled "Cardiac Tissue Penetrating Devices, Methods, and Systems for Treatment of Congestive Heart Failure and Other Conditions," filed May 20, 2014, which is related to and claims the benefit of U.S. Provisional Patent Application No. 61/827,114 entitled "Cardiac Tissue Penetrating Devices, Methods, and Systems for Treatment of Congestive Heart Failure and Other Conditions," filed May 24, 2013, the full disclosures of which are incorporated herein by reference in their entirety.

BACKGROUND OF THE INVENTION

The present invention is related to improved medical devices, systems, and methods, with many embodiments being particularly useful for reducing the distance between two points in tissue in a minimally or less invasive manner. Specific reference is made to the treatment of a failing heart, particularly the alleviation of congestive heart failure and other progressive heart diseases. The provided devices, systems, and methods will often be used to resize or alter the geometry of a ventricle in a failing heart, such as by reducing its radius of curvature through the process of excluding a portion of the circumference from contact with blood, and thereby reduce wall stress on the heart and improve the heart's pumping performance. Although specific reference is made to the treatment of congestive heart failure, embodiments of the present invention can also be used in other applications in which tissue geometry is altered.

Exemplary embodiments described herein provide implants and methods for alleviating congestive heart failure and other progressive diseases of the heart. Congestive heart failure may, for example, be treated using one or more implants which are selectively positioned relative to a first wall of the heart (typically an interventricular septum), and another wall of the heart so as to exclude scar tissue and limit a cross sectional area, or distance across a ventricle. Functional deterioration of the heart tissues may be inhibited by decreasing a size of the heart chamber and/or approximating tissues so that stress on the tissues is limited. Implant locations and overall chamber remodeling achieved by placement of a series of implants may be determined so as to provide a beneficial volumetric decrease and chamber shape.

Congestive heart failure (sometimes referred to as "CHF" or "heart failure") is a condition in which the heart does not pump enough blood to the body's other organs. Congestive heart failure may in some cases result from narrowing of the arteries that supply blood to the heart muscle, high blood pressure, heart valve dysfunction due to degenerative processes or other causes, cardiomyopathy (a primary disease of the heart muscle itself), congenital heart defects, infections of the heart tissues, and the like. However, in many cases congestive heart failure may be triggered by a heart attack or myocardial infarction. Heart attacks can cause scar tissue that interferes with the heart muscle's healthy function, and that scar tissue can progressively replace more and more of the contractile heart tissue. More specifically, the presence of the scar may lead to a compensatory neuro-hormonal response by the remaining, non-infarcted myocardium leading to progressive dysfunction and worsening failure.

People with heart failure may have difficulty exerting themselves, often becoming short of breath, tired, and the like. As blood flow out of the heart decreases, pressure within the heart increases. Not only does overall body fluid volume increase, but higher intracardiac pressure inhibits blood return to the heart through the vascular system. The increased overall volume and higher intracardiac pressures result in congestion in the tissues. Edema or swelling may occur in the legs and ankles, as well as other parts of the body. Fluid may also collect in the lungs, interfering with breathing (especially when lying down). Congestive heart failure may also be associated with a decrease in the ability of the kidneys to remove sodium and water, and the fluid buildup may be sufficient to cause substantial weight gain. With progression of the disease, this destructive sequence of events can cause the progressive deterioration and eventual failure of the remaining functional heart muscle.

Treatments for congestive heart failure may involve rest, dietary changes, and modified daily activities. Various drugs may also be used to alleviate detrimental effects of congestive heart failure, such as by dilating expanding blood vessels, improving and/or increasing pumping of the remaining healthy heart tissue, increasing the elimination of waste fluids, and the like.

Surgical interventions have also been applied for treatment of congestive heart failure. If the heart failure is related to an abnormal heart valve, the valve may be surgically replaced or repaired. Techniques also exist for exclusion of the scar and volume reduction of the ventricle. These techniques may involve (for example) surgical left ventricular reconstruction, ventricular restoration, the Dor procedure, and the like. If the heart becomes sufficiently damaged, even more drastic surgery may be considered. For example, a heart transplant may be the most viable option for some patients. These surgical therapies can be at least partially effective, but typically involve substantial patient risk. While people with mild or moderate congestive heart failure may benefit from these known techniques to alleviate the symptoms and/or slow the progression of the disease, less traumatic, and therefore, less risky therapies which significantly improve the heart function and extend life of congestive heart failure patients has remained a goal.

It has been proposed that an insert or implant be used to reduce ventricular volume of patients with congestive heart failure. With congestive heart failure, the left ventricle often dilates or increases in size. This can result in a significant increase in wall tension and stress. With disease progression, the volume within the left ventricle gradually increases and blood flow gradually decreases, with scar tissue often taking up a greater and greater portion of the ventricle wall. By implanting a device which brings opposed walls of the ventricle into contact with one another, a portion of the ventricle may be excluded or closed off. By reducing the overall size of the ventricle, particularly by reducing the portion of the functioning ventricle chamber defined by scar tissue, the heart function may be significantly increased and the effects of disease progression at least temporarily reversed, halted, and/or slowed.

BRIEF SUMMARY OF THE INVENTION

The present invention generally provides improved medical devices, systems, and methods. Exemplary embodiments of the devices are described for use in reducing the distance between a region along the septum and a region of an

external wall of the left ventricle of a heart in a less or minimally invasive manner. According to one embodiment, a tissue penetrating device is provided. The tissue penetrating device includes an elongate shaft having a proximal end, a distal end, a lumen extending between the proximal end and a distal end. The proximal end may be positioned outside a patient's body while the distal end is positioned within the patient's body, such as adjacent an organ (e.g., a heart) or tissue of the patient. The tissue penetrating device also includes a first needle disposed within the lumen of the elongate shaft. The first needle is extendable distally of the elongate shaft's distal end between a first configuration and a second configuration. The first needle has a proximal end, a distal end, and a lumen extending between the proximal end and a distal end. In the first configuration, the needle is disposed within the elongate shaft's lumen and is substantially aligned with an axis of the elongate shaft's lumen. In the second configuration, the first needle is extended distally of the elongate shaft's distal end and bends or curves away from the axis of the elongate shaft's lumen. The tissue penetrating device further includes a second needle that is disposed within the first needle's lumen. The second needle is extendable distally from the distal end of the first needle when the first needle is positioned in the first configuration and is also extendable distally from the distal end of the first needle when the first needle is positioned in the second configuration. The second needle may be extended distally from the first needle to penetrate tissue of the patient, such as a wall of a heart or other organ.

In some embodiments, the second needle may have a proximal end, a distal end, and a lumen extending between the proximal end and a distal end. In such embodiments, a guidewire may be inserted through the lumen of the second needle and into the patient's body, such as into a chamber of the patient's heart. In some embodiments, the second needle may be configured to measure or monitor fluid pressure within the patient's body. The fluid pressure may be measured or monitored to determine a location within a heart chamber of the patient (e.g., measure or monitor left ventricle heart pressure, right ventricle heart pressure, and/or damped pressure due to the needle being imbedded within the tissue walls of the heart).

In some embodiments, the tissue penetrating device may additionally include a tool body that is positioned at the proximal end of the elongate shaft. The tool body may be configured to be grasped by a physician to enable the physician to extend the first needle and the second needle so as to penetrate the patient's tissue. The tool body may include a first trigger member or mechanism that is slidable axially along the tool body to extend and retract the first needle relative to the elongate shaft's distal end. The tool body may also include a second trigger member or mechanism that is operable independently of the first trigger member or mechanism. The second trigger member or mechanism may be slidable axially along the tool body to extend and retract the second needle relative to the first needle. In some embodiments, the elongate shaft may be a catheter device.

In some embodiments, the tool body may include a spring trigger mechanism that causes the first needle and/or the second needle to rapidly deploy distally upon actuation of the spring trigger mechanism. In some embodiments, the distal end of the elongate shaft may include a locking mechanism that is couplable with an attachment or tissue anchoring device that may be removably attached to the patient's tissue or organ (e.g., the heart). In some embodiments, when in the second configuration, the first needle may bend or curve away from the axis of the elongate shaft's lumen by between about 45 and 210°. In other embodiments, the first needle may bend or curve away from the axis of the elongate shaft's lumen by between about 80 and 90°. In some embodiments, the distal end of the first needle and/or second needle may include a fluid pathway that allows the user to monitor or measure pressure within the patient's body, such as within a chamber of the heart. Monitoring or measuring pressure may allow the location of the tip of the needle to be determined. For example, left ventricle heart pressure may be monitored or measured, right ventricle heart pressure may be monitored or measured, and/or a damped pressure may be monitored or measured when the needle is imbedded within the wall of the heart (e.g., septum wall). This may allow a physician to determine that the needle tip is near or within the corresponding heart chamber or within heart tissue. In some embodiments, the distal end of the first needle and/or second needle may include a pressure transducer that may be used to sense pressure in or around the patient's tissue or organ, such as in or around the heart as described above.

According to another embodiment, a method of penetrating tissue of a patient is provided. The method includes providing a tissue penetrating device, where the tissue penetrating device includes: an elongate shaft having a proximal end, a distal end, and a lumen extending between the proximal end and a distal end; a first needle disposed within the lumen of the elongate shaft and extendable distally of the elongate shaft's distal end between a first configuration and a second configuration, the first needle having a proximal end, a distal end, and a lumen extending between the proximal end and a distal end; and a second needle disposed within the first needle's lumen and extendable therefrom. The method also includes advancing the first needle distally of the elongate shaft's distal end so as to position the first needle's distal end adjacent the patient's tissue. The first needle may bend or curve away from an axis of the elongate shaft's lumen as the first needle extends distally of the elongate shaft's distal end. The method further includes advancing the second needle distally of the first needle's distal end so as to penetrate the patient's tissue with the second needle.

In some embodiments, the second needle may include a proximal end, a distal end, and a lumen extending between the proximal end and a distal end. In such embodiments, the method may further include inserting a guidewire through the lumen of the second needle and into the patient's body. In some embodiments, advancing the first needle may include actuating a first trigger mechanism of a tool body, where the tool body is positioned at a proximal end of the elongate shaft and is configured to be operated by a physician. In some embodiments, advancing the second needle may include actuating a second trigger mechanism of the tool body. The second trigger mechanism may be operable independently of the first trigger mechanism. In some embodiments, the first trigger mechanism and/or the second trigger mechanism may include a spring trigger mechanism that causes the first needle and/or the second needle to rapidly deploy upon actuation of the spring trigger mechanism. In other embodiments, advancing the first needle and/or second needle may include actuating a trigger mechanism that causes the first needle to be pneumatically advanced via pressurized fluids. In some embodiments, the elongate shaft may be a catheter device.

According to another embodiment, a method of penetrating cardiac tissue for treatment of congestive heart failure is provided. The method includes positioning a proximal end

of the elongate shaft adjacent an external wall of the patient's heart. A distal end of the elongate shaft may be positioned outside of the patient's body. The method also includes advancing a needle distally of a distal end of the elongate shaft and through the external wall, where the needle is disposed centrally within a lumen of the elongate shaft. The method further includes advancing a sleeve, or outer needle, over the needle and through the external wall, where the sleeve is disposed within the lumen of the elongate shaft and is coaxially aligned with the needle. The method additionally includes advancing the sleeve distally of the external wall to position the sleeve and needle adjacent the septal wall of the patient's heart. As the sleeve is advanced distally of the external wall, the sleeve may curve or bend away from an axis of the elongate shaft's lumen. The method may additionally include advancing the needle distally of the distal end of the sleeve and through the septal wall of the patient's heart.

In some embodiments, the guidewire may be inserted through a lumen of the needle and through the external wall and septal wall so that the guidewire is positioned within a chamber of the heart. The guidewire may be joined with a snare that has been inserted within the chamber of the heart along a different path than that of the guidewire. Joining the guidewire and the snare may couple the paths of the guidewire and the snare. The method may additionally include advancing a first anchor and an elongate tension member into the chamber along the joined paths of the guidewire and snare. The first anchor may be positioned distally of the septal wall and the tension member may extend from the septal wall, through the external wall and septal wall, and outside the patient's body.

The method may additionally include coupling a second anchor (e.g., an epicardial anchor) to the tension member, advancing the second anchor along the tension member to a position proximate the external wall, and applying tension between the first anchor and the second anchor so that the anchors urge the septal wall and external wall to engage. In some embodiments, the sleeve may be an outer needle that is slidable over the needle and disposed within the elongate shaft's lumen. In some embodiments, the method may additionally include sensing a pressure with a distal end of the needle and/or sleeve via a fluid pathway of the needle and/or sleeve, or via a pressure transducer of the needle and/or sleeve. In some embodiments, the elongate shaft may be a catheter device.

According to another embodiment, a method of penetrating tissue of a patient is provided. The method includes positioning a proximal end of an elongate shaft adjacent tissue of a patient (e.g., an external wall of the patient's heart). The method also includes advancing a needle distally of a distal end of the elongate shaft and through the tissue. Prior to advancement of the needle, the needle may be disposed centrally within a lumen of the elongate shaft and an axis of a distal tip of the needle may be substantially aligned with an axis of the lumen. The method further includes advancing the distal tip of the needle distally of the tissue to position the distal tip adjacent additional tissue of the patient (e.g., a septal wall of the patient's heart). The method additionally includes causing the needle to be flexed as the needle is advanced distally of the tissue so that the axis of the distal tip of the needle bends or curves away from the axis of the lumen. The method additionally includes advancing the needle through the additional tissue of the patient (e.g., through the septal wall).

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention is described in conjunction with the appended figures:

FIG. **1** illustrates a front and side view of a tissue penetrating device according to an embodiment.

FIG. **2** illustrates a perspective view of the tissue penetrating device of FIG. **1**.

FIGS. **3**A-**3**C illustrate the tissue penetrating device of FIG. **1** with an inner and outer needle retracted within an elongate shaft according to an embodiment.

FIGS. **4**A-**4**C illustrate the tissue penetrating device of FIG. **1** with the inner needle extending from the elongate shaft according to an embodiment.

FIGS. **5**A-**5**C illustrate the tissue penetrating device of FIG. **1** with the outer needle extending from the elongate shaft according to an embodiment.

FIGS. **6**A-**6**C illustrate the tissue penetrating device of FIG. **1** with the outer needle extending from the elongate shaft and with the inner needle extending from the outer needle according to an embodiment.

FIG. **7**A illustrates a reconstructed left ventricle using a series of implanted anchors so as to mitigate the deleterious effects of congestive heart failure, according to an embodiment.

FIG. **7**B illustrates a cross-sectional view of the heart of FIG. **7**A, showing a reduction in the size of the left ventricle effected by one of the implants.

FIGS. **7**C and **7**D illustrate minimally invasive access to and endoscopic imaging of a pericardium of the heart.

FIG. **7**E illustrates joining of a femoral access tool path through the right atrium and an endoscopic trans-epicardial access tool path by snaring a guidewire within the right ventricle of the heart.

FIG. **8**A illustrates a trocar or shaft positioned adjacent an external wall of a heart in a treatment for congestive heart failure according to an embodiment.

FIG. **8**B illustrates an inner needle penetrating through the external wall of the heart in the congestive heart failure treatment.

FIG. **8**C illustrates an outer needle being positioned adjacent the septal wall of the heart in the congestive heart failure treatment.

FIG. **8**D illustrates the inner needle penetrating through the septal wall of the heart in the congestive heart failure treatment.

FIG. **8**E illustrates a guidewire being inserted into the right ventricle of the heart so as to be snared by a snare device and join paths of the guidewire and snare device in the congestive heart failure treatment.

FIG. **8**F illustrates the joined paths of the guidewire and snare device in the congestive heart failure treatment.

FIG. **8**G illustrates a septal anchor positioned adjacent the septal wall and a tension member extending through the septal wall and external wall in the congestive heart failure treatment.

FIG. **8**H illustrates an epicardial anchor being slid distally along the tension member and adjacent the external wall of the heart in the congestive heart failure treatment.

FIG. **8**I illustrates the septal anchor and epicardial anchor being used to reconfigure the shape of the heart and the volume of the left ventricle in the congestive heart failure treatment.

FIG. **9**A illustrates a cross section view of a tissue penetrating device having a spring actuated triggering mechanism according to an embodiment.

FIGS. **9**B-E illustrate enlarge cross section views of the tissue penetrating device of FIG. **9**A.

In the appended figures, similar components and/or features may have the same numerical reference label. Further, various components of the same type may be distinguished

by following the reference label by a letter that distinguishes among the similar components and/or features. If only the first numerical reference label is used in the specification, the description is applicable to any one of the similar components and/or features having the same first numerical reference label irrespective of the letter suffix.

DETAILED DESCRIPTION OF THE INVENTION

The present invention generally provides improved medical devices, systems, and methods. Exemplary embodiments of the devices are described for use in reducing the distance between a region along the septum and a region of an external wall of the left ventricle of a heart in a less or minimally invasive manner. Hence, embodiments of the tools and methods described herein may find specific use in the treatment of congestive heart failure and other progressive heart diseases by reconfiguring abnormal heart geometry that may be contributing to heart dysfunction. For congestive heart failure therapies, perforating both the exterior wall and the septum from an epicardial approach can provide significant benefits in control over the locations of implant deployments, thereby effectively enhancing the resulting reshaping of the ventricular chamber. Despite this largely epicardial approach, there are surprising benefits to guiding deployment of the implant from along both the epicardial access path and another access path into and via an access path through the right ventricle. This additional right atrial access path into the heart may be via the superior vena cava, the inferior vena cava, the right atrial appendage, or the like, and the pathways may be joined together by coupling of a snare to a guidewire or the like within the right ventricle, the right atrium, the right pulmonary artery, or the like. While a variety of tools will be described herein for providing access pathways, for joining pathways together within the heart, for deploying implants, for maintaining hemostasis, and the like, it should be recognized that alternative embodiments may employ additional or alternative structures, some of which may be off-the-shelf, and some of which may be new structures configured particularly for use in the advantageous therapies described herein.

Joining pathways may be accomplished by using a guidewire and snare device. To join the pathways, the guidewire is often inserted through the external wall and septal wall of the heart. The external wall and/or septal wall are often composed of relatively tough scar tissue, which makes insertion of the guidewire through these walls relatively challenging. For example, relatively thin and long needles (e.g., 17 Gauge (0.058")) are often used to penetrate the scar tissue of the external and/or septal walls. The needles need to be relatively long to allow a physician to position the needle through a small incision, through the external wall, and through the septal wall. These thin and long needles often bend or buckle as they are pressed firmly against the tough scar tissue, which complicates the wall penetrating processes. Further, the needle insertion locations for the external wall and septal wall are typically not aligned relatively to one another. Rather, the insertion locations are often angled or offset from one another by some degree. As such, straight needles are often relatively difficult to maneuver and/or work with in penetrating both the external wall and the septal wall.

The tissue penetrating devices described herein are able to easily penetrate tough scar tissue while compensating for the offset insertion locations of the external and septal wall. This is accomplished by providing a needle and sleeve combination, or a pair of needles, that are coaxially aligned and that slide relative to one another. The needle (hereinafter inner needle) is a small sharp needle that is used to initially penetrate the tough scare tissue of the external wall and septal wall. In initially penetrating the scar tissue, a sleeve or outer needle (hereinafter outer needle) is positioned adjacent the scar tissue and over the inner needle. In this manner the outer needle supports the inner needle and prevents or reduces bending and/or buckling of the inner needle during insertion of the inner needle through the tough scar tissue. After the inner needle penetrates the scar tissue, the outer needle may then be advanced over the inner needle and through the tough scar tissue of the external wall or septal wall.

The outer needle may be made of a flexible shape-memory material, such as nitinol, that is able to bend or flex as the outer needle is advanced distally of a distal end of a surgical device's an elongate shaft. The flexible shape-memory material allows the outer needle to bend away from the insertion location of the external wall and toward the insertion location of the septal wall after the outer needle is inserted through and advanced distally of the external wall. In this manner, the inner needle may be positioned adjacent and used to penetrate through the offset insertion locations of the external wall and septal wall. The outer needle may be configured to have any desired degree of bend so as to accommodate patients of various shape and size. The inner needle may likewise be made of a flexible material, such as nitinol, to allow the inner needle to be advanced within a lumen of the outer needle without significantly altering the bend or flexed configuration of the outer needle. The outer and inner needle may be positioned adjacent a desired insertion point on the septal wall and the inner needle may be advanced distally of the outer needle and through the septal wall. A guidewire may then be inserted through a lumen of the inner needle, through the external wall and septal wall, and into a chamber of the heart for snaring and joining insertion paths as described herein.

For convenience in describing the embodiments herein, the sleeve or outer component is referred to herein as an "outer needle." It should be realized, however, that the outer component is not limited to needles and that other types of component may be used, such as: a sleeve, catheter, elongate shaft, or tube that is configured to track over the inner needle and bend or flex as described herein. In some embodiments, however, the outer component may be a needle that is capable to some degree of insertion through tissue with or without the assistance of the inner needle. Having generally described some embodiments, additional feature of the embodiments will be recognized with reference to the figures described below.

Referring now to FIG. **1**, illustrated is a tissue penetrating device **100** that may be used to penetrate various tissue of the patient, such as an external wall and/or septal wall of a heart. Tissue penetrating device **100** includes a tool body **102** that may be grasped by a physician during a tissue penetrating operation. Attached to body **102** is a pair of finger guides **104** through which the physician may insert his or her fingers. A second finger guide **106**, or trigger mechanism, is also slidably coupled with body **102**. Finger guide **106** is able to slide axially along body **102** via track **116** to deploy and retract an outer needle **120** relative to an elongate shaft **110** of device **100**. A second trigger mechanism **108** is also slidably coupled with body **102**. Second trigger mechanism **108** is axially movable along body **102** via track **116** to deploy and retract an inner needle (**122** of FIG. **2** and the like) relative to elongate shaft **110** and outer needle **120**.

Second trigger mechanism **108** is typically operable independently of first trigger mechanism **106** so that the inner needle **122** and outer needle **120** are independently deployable and retractable to at least some degree relative to one another. Body **102** also includes one or more ports, **112** and **114**, through which a guidewire, tether or tension member, and the like may be inserted; or which may function to fluidly couple a pressure sensing fluid pathway with an external pressure monitoring or measuring device (not shown).

Outer needle **120** and inner needle **122** are disposed within a lumen of the elongate shaft **110** and are slidable relative thereto so as to be extendable from and retractable within the lumen of elongate shaft **110**. Further, outer needle **120** and the inner needle **122** are coaxially aligned and slidable relative to one another. Outer needle **120** is disposed over inner needle **122** with inner needle **122** being slidably disposed within a lumen of outer needle **120**. Inner needle **122** is extendable distally beyond a distal end of outer needle **120** and retractable within the lumen of outer needle **120**.

FIG. **2** shows a perspective view of another embodiment of tissue penetrating device **100**. FIG. **2** illustrates the finger guides **104** positioned at a proximal end of body **102**. FIG. **2** further illustrates the second finger guide **106** slid proximally away from finger guides **104**, which typically results in outer needle **120** and inner needle **122** being retracted within the lumen of elongate shaft **110**. For illustrative purposes, however, outer needle **120** is shown being extended distally of elongate shaft **110** even though the second finger guide **106** is slid proximally away from finger guides **104**. FIG. **2** additionally shows that the second trigger mechanism **108** may be coupled with a shaft or tube that is slidable within body **102** and/or within a shaft or tube of first trigger mechanism **106**. The shaft or tube of the second trigger mechanism **108** and/or the shaft or tube of the first trigger mechanism **106** may include locking components **117** that help maintain the position of the second trigger mechanism's shaft or tube and/or first trigger mechanism's shaft or tube relative to one another and/or to body **102**. In some embodiments, the locking component **117** may help maintain a positional relationship between the inner needle **122** and the outer needle **120**. For example, as the outer needle **120** is advanced distally of the distal end of elongate shaft **110**, the inner needle **122** may remain in position until the distal tips of both the inner needle **122** and the outer needle **120** substantially align. Afterward, the locking component **117** may lock the first and second trigger mechanisms, **106** and **108**, together so that further advancement of the outer needle **120** causes the inner needle **122** to also advance.

FIG. **2** additionally shows that an outer sleeve **130** may be slidably disposed over elongate shaft **110**. Outer sleeve **130** may include a locking mechanism **132** that is couplable with a tissue anchoring device (not shown) that is positioned adjacent and/or removably coupled with tissue or an organ of the body (e.g., the heart) through which the inner needle **122** and/or outer needle **120** are to be inserted. As shown in FIGS. **1** and **2**, when axially extended from the elongate shaft **110**, the outer needle **120** bends, flexes, or curves away from an axis of the elongate shaft **110**'s lumen. As described herein, outer needle **120** may be made of a flexible shape-memory material, such as nitinol, that is configured to automatically bend or curve by a radius R as the outer needle **120** is advanced distally of a distal end of an elongate shaft **110**. The flexible material of outer needle **120** also allows the outer needle to straighten when the outer needle **120** is retracted within the elongate shaft **110**'s lumen. When retracted within elongate shaft **110**'s lumen, outer needle **120** is substantially aligned with the axis of elongate shaft **110**'s lumen. The radius of curvature R may be selected such that when the outer needle **120** is advanced distally from a distal end of elongate shaft **110**, a distal end of outer needle **120** is curved or bent away from the axis of the elongate shaft **110**'s lumen by between 45 and 210 degrees, and more commonly by about 80 and 120 degrees, so as to enable the distal end of outer needle **120** and/or inner needle **122** to be positioned at offset insertion locations of the external and septal walls. In one embodiment, the radius of curvature R may be between about 10 and 38 mm. This radius of curvature range of outer needle **120** is found to be sufficient for the majority of patients.

In some embodiments, the radius of curvature R and/or degree of bend of the outer needle **120** may be dynamically adjusted. For example, when the outer needle **120** is made of nitinol, the radius of curvature R and/or bend of the outer needle **120** may be adjusted by varying the temperature of the needle. The temperature of the nitinol needle may be varied while the needle is within, or external to, the patient's body. The temperature of the nitinol needle may be varied automatically (e.g., by the patient's body temperature) or in a controlled manner (e.g., via resistive heating of the needle and the like). This variation and control of the outer needle **120**'s shape may allow a physician to adjust the needle to fit or conform to a specific patient's geometry and/or allow a single needle to be used in multiple instances, such as to place multiple anchors when treating congestive heart failure.

The inner needle **122** is similarly made of a flexible material, such as nitinol, that allows the inner needle **122** to curve, flex, or bend by radius R as the inner needle **122** is advanced simultaneously with outer needle **120**, or slid within the lumen of outer needle **120**. The flexibility of the inner needle **122** prevents the inner needle **122** from significantly straightening or otherwise affecting the radius of curvature R of outer needle **120**. Stated differently, because the inner needle **122** is also made of a flexible material, the inner needle **122** may be advanced simultaneously with outer needle **120**, or slid within the lumen of outer needle **120**, and bent, flexed, or forced to curve by the outer needle **120** as the outer needle **120** is advanced distally from elongate shaft **110**. As described herein, the inner needle does not significantly straighten or otherwise affect the radius of curvature R of the outer needle. It should be realized that some straightening or change in the radius of curvature R may occur, but that any such change is slight and not significant enough to greatly affect the positioning of the outer and inner needle relative to the heart. The flexibility of inner needle **122** also allows the inner needle **120** to be straightened when the inner needle **122** and/or outer needle **120** are retracted within elongate shaft **110**'s lumen. When retracted within the lumen of elongate shaft **110**, inner needle **122** is substantially aligned with the axis of the elongate shaft **110**'s lumen.

The dual needle arrangement of the tissue penetrating device **100** stabilizes the inner needle **122** as the inner needle **122** is inserted through bodily tissue of the patient. Since both the inner needle **122** and the outer needle **120**, which is coaxially aligned with and positioned over inner needle **122**, are positioned adjacent the patient's tissue that is to be penetrated with inner needle **122**, the outer needle **120** provides a relatively rigid sheath that reinforces the inner needle **122** as the inner needle is penetrated through the patient's tissue. This configuration prevents or reduces buckling or bending of the inner needle **122** as the inner

needle **122** is inserted through the patient's tissue. This configuration also allows the penetrating force of the inner needle **122** to be concentrated at a distal tip of the inner needle **122**, thereby enabling the inner needle **122** to easily puncture through tough scar tissue or other tissue, which may otherwise cause bending or buckling of the inner needle **122**.

Although not shown in FIGS. **1** and **2**, in some embodiments the first trigger mechanism **106** and/or second trigger mechanism **108** may be spring-loaded such that actuation of the first trigger mechanism **106** and/or second trigger mechanism **108** causes a spring to rapidly fire or deploy the outer needle **120** and/or inner needle **122** across the tissue of the patient (see FIGS. **9**A-E). Spring-loading the first trigger mechanism **106** and/or second trigger mechanism **108** may allow the inner needle **122** and/or outer needle **120** to easily penetrate relatively tough scar tissue or other tissue. Spring-loading of the trigger mechanisms, however, is typically not necessary and in fact may not be desired, since the support provided by the outer needle **120** allows the inner needle **122** to easily penetrate tough scar tissue and other tissue. In other embodiments, the first and/or second trigger mechanism may include a pneumatic mechanism that causes the inner needle **122** and/or outer needle **120** to be advanced via pressurized fluids.

In some embodiments, inner needle **122** may be an approximately a 21 Gauge (0.033 in) needle while outer needle **120** is a slightly larger needle, such as a 17.5 Gauge (0.054 in) needle and the like. The dimensions of the needles may be adjusted based on need, patient size, application, procedure, or as otherwise desired. In some embodiments, an outer diameter of elongate shaft **110** and/or outer sleeve **130** is smaller than about 5 mm or 7.5 mm to allow the elongate shaft **110** and/or outer sleeve **130** to be inserted through a 5 mm or 7.5 mm trocar that is positioned through a relatively small incision in the patient's skin.

In some embodiments, the distal end of elongate shaft **110** may include a joint member (see **126** of FIG. **3**C and the like) that is couplable with a tissue anchoring or attachment device (not shown) that is positioned on or adjacent tissue to be penetrated with inner needle **122**. The joint member **126** may allow the elongate shaft **110** and body **102** to be aligned relative to the tissue anchoring device by some degree, such as up to between about 10 and 30 degrees. This allows the distal tip of elongate shaft **110** to be positioned adjacent the tissue to be penetrated with inner needle **122** and for the tissue penetrating device **100** to be offset so that the inner needle **122** will penetrate the tissue at a desired angle and/or so that the outer needle **120** will be positioned adjacent a desired insertion location of additional tissue after the outer needle **120** is advanced from elongate shaft **110** and flexed or curved by radius R. The joint member **126** allows the outer needle **120** and inner needle **120** to be steered posterior or anterior to the heart, or some feature of the heart. For example, the alignment of the elongate shaft **110** relative to the tissue anchoring device and heart may be adjusted so that a tip of the outer needle **120** (i.e., in a bent or straight configuration) and/or the inner needle **122** may be positioned closer to a heart's apex, base, valve, septal or exterior wall, and the like as desired. This effectively allows the outer and/or inner needle's tip to be steered within or relative to a patient's heart or other tissue as needed or desired, which facilitates in precise placement and/or penetration of the needles relative to the tissue. Steering of the outer needle **120** and/or inner needle **122** may be further facilitated via the use of an imaging device (e.g., a thoracoscope, fluoroscope, and the like).

In one embodiment, when the tissue penetrating device **100** is used for treating congestive heart failure, the tissue penetrating device **100** may be aligned so that the distal tip of elongate shaft **110** and/or outer needle **120** is positioned toward an apex of the heart, toward a base of the heart, and/or toward any other desired feature of the heart. In some embodiments, the distal tip of outer needle **120** and/or inner needle **122** may be radiopaque so that the distal tip is easily identifiable via an imaging device (e.g., a thoracoscope, fluoroscope, and the like). Further, the locking mechanism **132** of outer sleeve **130** may couple the elongate shaft **110** with the tissue anchoring device and the joint member **126** may allow some degree off-axis of the elongate shaft **110** relative to the tissue anchoring device.

In still other embodiments, the distal tip of the outer needle **120** and/or inner needle **122** may include a fluid pathway that allows a physician to monitor or measure pressure within the patient's body, such as within a chamber of the heart. Monitoring or measuring pressure may allow the location of the tip of the needle within the patient's body to be determined. In other embodiments, the distal tip of the needle **120** and/or inner needle **122** may include a pressure transducer that allows a pressure within the patient to be measured or determined as either or both needles are inserted through tissue of the patient and/or within one or more chambers within the body. For ease in describing the embodiments herein, the needle's pressure sensing fluid pathway, pressure transducer, and the like, will be referred to hereinafter as a pressure sensing element.

In one embodiment, when the tissue penetrating device **100** is used for treating congestive heart failure, the pressure sensing element (e.g., fluid pathway and the like) may be used to determine when the inner needle **122** and/or outer needle **120** have penetrated through the external wall of the heart, when the inner needle **122** and/or outer needle **120** are positioned within a chamber of the heart, when the inner needle **122** and/or outer needle **120** are positioned adjacent a septal wall of the heart, and/or when the inner needle **122** has penetrated through the septal wall and is positioned within the right ventricle of the heart. For example, the pressure sensing element may be used to measure or monitor left ventricle heart pressure, right ventricle heart pressure, and/or a damped pressure that corresponds to when the needle is imbedded within the wall of the heart (e.g., septum wall). The pressure sensing element may also be used to determine when the inner needle **122** and/or outer needle **120** are positioned adjacent scar tissue or contractile tissue of the heart to enable the physician to determine if the inner needle **122** and/or outer needle are adjacent a desired insertion point. In a specific embodiment, the inner needle **122** includes the pressure sensing element and the inner needle is used to sense pressure within the heart and/or elsewhere within the patient's body.

Referring now to FIGS. **3**A-**6**B, illustrated is an embodiment of the operation of a tissue penetrating device **100**. Specifically, FIGS. **3**A-**3**C illustrate the first trigger mechanism **106** and the second trigger mechanism **108** being positioned in a proximal position relative to body **102** such that the inner needle **122** and outer needle **120** are fully retracted and disposed within the lumen of elongate shaft **110**. As shown in FIG. **3**C, a distal tip of the inner needle **122** may be positioned adjacent a distal tip of elongate shaft **110**, or axially extend partially therefrom. FIG. **3**C also illustrates the outer sleeve **130**, locking mechanism **132**, and joint member **126** in greater detail.

FIGS. **3**A-**3**C further illustrate an alignment sleeve **131** that may be positioned near the distal end of outer sleeve **130**

to coaxially align the outer sleeve **130** with a trocar or access tube that is positioned within the patient's body. As is known in the art, a trocar or access tube may be inserted within a small incision within the body, often between two ribs, and used as a port for inserting and removing catheters and/or other surgical devices from the body. Alignment sleeve **131** aligns the outer sleeve **130** within such a trocar or access tube to enable easy coupling of the locking mechanism **132** within a tissue anchoring device (not shown) that is positioned adjacent the heart or other organs. In some embodiments, alignment sleeve **131** is slidable about outer sleeve **130**, while in other embodiments, alignment sleeve **131** is relatively fixed about outer sleeve **130**. In some embodiments, locking mechanism **132** may comprise threads that may be threaded with a corresponding aperture of the tissue anchoring device. FIG. **3**B illustrates an enlarged perspective view of body **102** and several components of the device **100** and illustrates that body **102** may include indicia that facilitates in informing a physician of the deployment of the outer needle **120** and/or inner needle **122**.

With the inner needle **122** and outer needle **120** fully retracted and disposed within the lumen of elongate shaft **110**, the distal tip of elongate shaft **110** may be positioned adjacent the patient's tissue to be penetrated with inner needle **122**, and/or the distal tip of elongate shaft **110** may be coupled with a tissue anchoring device (not shown) that is positioned adjacent the patient's tissue. After the distal tip of elongate shaft **110** is positioned adjacent the patient's tissue, second trigger mechanism **108** may be slid distally along body **102** to axially advance inner needle **122** from the lumen of elongate shaft **110** and outer needle **120**. The second trigger mechanism **108** may be slid distally along body **102** by placing a finger (e.g., a forefinger) within the first trigger mechanism **106** and by pressing on the second trigger mechanism **108** with another finger (e.g., a thumb). FIGS. **4**A-**4**C illustrate the inner needle **122** extended from elongate shaft **110** after the second trigger mechanism **108** is slid distally along body **102**. As shown in FIG. **4**A, second trigger mechanism **108** is positioned directly adjacent the first trigger mechanism **106** after second trigger mechanism **108** is slid distally along body **102**.

Advancing the inner needle **122** from elongate shaft **110** as shown in FIG. **4**C causes the inner needle **122** to penetrate through tissue positioned adjacent the distal tip of elongate shaft **110**. In this configuration, first trigger mechanism **106** may be slid distally along body **102** to cause the outer needle **120** to slide within the lumen of elongate shaft **110** and advance distally from elongate shaft **110**. Sliding the first trigger mechanism **106** distally along body **102** may be performed by placing a finger or fingers within finger guides **104** and by pressing on first trigger mechanism **106** with another finger. FIGS. **5**A-**5**C illustrate the outer needle **120** extending from the distal end of elongate shaft **110** after the first trigger mechanism **106** is slid distally along body **102**.

As shown, the inner needle **122** may be retracted within an outer needle **120** as the first trigger mechanism **106** is slid distally along body **102**. Retraction of the inner needle **122** may occur automatically as the first trigger mechanism **106** is slid along body **102**. For example, the inner needle **122** may remain in position as the outer needle **120** is advanced until the distal tips of the inner needle and outer needle substantially align. Afterwards, advancement of the outer needle **120** may cause the inner needle **122** to also advance so that the distal tips of the inner needle **122** and outer needle **120** remain substantially aligned. In other embodiments, the retraction of inner needle **122** may be a manual process that is performed by a physician, such as by holding the second trigger mechanism **108** in place as first trigger mechanism **106** is slid distally along body **102**, or by sliding second trigger mechanism **108** proximally along body **102**. As shown in FIG. **5**B and as described herein, outer needle **122** bends or curves away from an axis of the lumen of elongate shaft **110** as the outer needle **120** is advanced distally away from the distal end of elongate shaft **110**. The distal end of outer needle **120** may be advanced away from the distal end of elongate shaft **110** until the distal end of outer needle **120** (and the distal end of inner needle **122**) is positioned adjacent tissue to be penetrated with inner needle **122**. As described herein, the outer needle **120** is made of a flexible shape-memory material and has a preconfigured curved that may be configured or selected to fit/accommodate a specific patient.

After the distal end of the outer needle **120**, and inner needle **122**, is positioned adjacent tissue to be penetrated with inner needle **122** (e.g., adjacent a septal wall), the second trigger mechanism **108** may be slid distally along body **102** to extend inner needle **122** beyond the distal end of outer needle **120** and thereby penetrate the patient's tissue. FIGS. **6**A-**6**C illustrate the second trigger mechanism **108** being slid distally along body **102** to extend inner needle **122** so as to penetrate tissue of the patient. FIG. **6**A also illustrates a track **116** within which the first trigger mechanism **106** and/or second trigger mechanism **108** may slide.

FIGS. **6**A-**6**C further illustrate a reinforcement sleeve **123** being slid over the outer needle **120**. The reinforcement sleeve **123** may reinforce the outer needle **120** and/or inner needle **122** as the inner needle **122** is extended from the distal end of outer needle **120**. Relatively substantial bending forces may be imparted to the outer needle **120** at or near where the outer needle **122** extends from the elongate shaft **110** as the inner needle **122** is being inserted through bodily tissue, such as through tough scar tissue. These bending forces may cause the outer needle **120** to bend or flex under the load, especially due to the outer needle **120** being made of the flexible shape-memory material. Flexing or bending of the outer needle **120** may hinder the inner needle's ability to penetrate the bodily tissue. Reinforcement sleeve **123** minimizes or greatly reduces bending or flexing of the outer needle **120** at or near where the outer needle **122** extends from the elongate shaft **110**. Rather, the bending forces are imparted to the reinforcement sleeve **123**, which may be made of stainless steel or another relatively rigid material that does readily bend or flex under load. In this manner, the outer needle **120** and inner needle **122** may be substantially reinforced as the inner needle **122** is extended from the flexed or curved outer needle **120**.

In some embodiments, the reinforcement sleeve **123** may be extended up to near where the outer needle **120** begins to bend, flex, or otherwise curve. The reinforcement sleeve **123** may be configured to automatically extend from the distal end of the elongate shaft **110** with the outer needle **120**, or may be extended separately therefrom. For example, operation of the first trigger mechanism **106** along body **102** may cause the outer needle **120** and reinforcement sleeve **123** to simultaneously extend from the distal end of elongate shaft **110**. The reinforcement sleeve **123** may be deployed or extended via first trigger mechanism **106** up to near the location that the outer needle **120** begins to bend or flex, after which further operation of the first trigger mechanism **106** may cause the outer needle **120** to extend independent of the reinforcement sleeve **123**. In other embodiments, a separate mechanism (not shown) may be used to deploy and retract reinforcement sleeve **123**.

Referring now to FIGS. **7**A-**8**I, a procedure for treating congestive heart failure using the tissue penetrating device **100** is illustrated. Specifically, FIGS. **7**A and **7**B illustrate a series of implants **10** implanted in a heart H so as to decrease a cross-section of a left ventricle LV. Each implant **10** generally includes a first anchor **12**, a second anchor **14**, and a tension member **16** coupling the anchors together. Tension in the tension member **16** is transferred from the anchors, **12** and **14**, to the septum S and the external wall EW bordering the left ventricle LV so as to bring these structures into engagement, thereby effectively excluding a region of scar tissue ST from the left ventricle. In many embodiments described herein, implant **10** will be deployed by penetrating the external wall EW and septum S via a pericardium P of the heart H, and also by accessing a right ventricle RV via a right atrium. Anchors deployed within a right ventricle and/or in engagement with the septum S may sometimes be referred to herein as septal anchors, while anchors deployed along the external wall EW of the left ventricle LV may be referred to as epicardial anchors.

Referring now to FIGS. **7**C and **7**D an MRI image I taken along viewing plane VP schematically illustrates use of a thoracoscope or fluoroscope **20** to provide a field of view encompassing a region of the pericardium of the heart, with the region including a target site for deployment of one or more epicardial anchors and/or septal anchors of the implant system.

Referring now to FIG. **7**E, joining of an access path through the right atrium to an access path through the pericardium and epicardium by snaring of a guidewire within the right ventricle under thoracoscopic/fluoroscopic guidance **20** is schematically illustrated. The right atrial access path may extend into the arterial vasculature via the femoral artery FA and inferior vena cava IVC, via the jugular artery JA via the superior vena cava, or the like. As can be understood with reference to FIG. **8**A, a selected location for perforation of the external wall EW can be identified using an image from thoracoscope/fluoroscope **20**, optionally in combination with an image from another imaging modality, such as a prior or contemporaneous image from an ultrasound imaging system, an MRI imaging system, an X-ray or fluoroscopic imaging system, a CT imaging system, or the like. In exemplary embodiments, a shaft **430** of an access tool having a working lumen there through is advanced through the epicardium of the beating heart so that a distal end of the shaft **430** is positioned adjacent the external wall EW of the heart. Shaft **430** may comprise a trocar and may have a proximal hemostasis valve at its proximal end so as to inhibit blood flow through the lumen and facilitate insertion and/or removal of elongate shaft **110** or outer sleeve **130** of tissue penetrating device **100**. Alignment sleeve **131** may be used to align the shaft **110** or outer sleeve **130** of device **100** with shaft **430**.

A catheter **404** is inserted into the arterial vasculature via the jugular artery JA and tricuspid valve; or in other embodiments, via the femoral artery FA and inferior vena cava IVC, via the superior vena cava, or the like. A snare device **402**, such as a wire hoop or wire basket, is positioned against the septum S at or adjacent an insertion point for inner needle **122**. Snare device **402** may be positioned against septum S by using an off-the-shelf steerable catheter **404**. The snare device **402** may provide a target for inner needle **122**. Snare device **402** may be easily visible via fluoroscopy **20** and provide a reference point for steering the inner needle **122** and/or outer needle **120**. As described herein, the distal tip of inner needle **122** and/or outer needle **120** may be radiopaque so that the distal tip of either or both needles is easily visible with a fluoroscope **20**.

Shaft **430** may be positioned adjacent the external wall EW by inserting the shaft **430** through an incision between ribs of the patient, such as between the fourth and fifth intercostal space. Although not shown in the figures, in some embodiments the tissue anchoring device may be inserted through a subxiphoid incision and positioned adjacent the external wall EW. The subxiphoid incision may be relatively small, such as a two or three finger incision. The tissue anchoring device may be coupled with the external wall EW and a distal end of the shaft **430**, or a distal end of elongate shaft **110**, may be coupled with the tissue anchoring device to attached and/or stabilize the shaft **430** and/or elongate shaft **110** adjacent the external wall EW. The thoracoscope/fluoroscope **20** may also be inserted through the subxiphoid incision.

As shown in FIG. **8**B, with the shaft **430** positioned adjacent external wall EW, the second trigger mechanism **108** may be actuated so as to advance inner needle **122** from the lumens of elongate shaft **110** and outer needle **120** in order to penetrate the external wall EW. A pressure sensing element of inner needle **122** (e.g., fluid pathway, pressure transducer, and the like) may be used to determine that the inner needle **122** is positioned adjacent the external wall EW and/or inserted through the external wall EW and into the left ventricle LV. As shown in FIG. **8**C, after the inner needle **122** is inserted through the external wall EW, the first trigger mechanism **106** may be actuated to extend the outer needle **120** distally of elongate shaft **110** and through external wall EW. The outer needle **120**, and inner needle **122**, may be advanced distally of elongate shaft **110** so that the outer needle **120** curves or bends away from an axis of the lumen of elongate shaft **110** and toward septum S. The inner needle **122** may be retracted within an outer needle **120** as the outer needle **120** is advanced toward septum S so as to prevent the inner needle **122** from penetrating other tissue of heart H. The outer needle **120** may be advanced until a distal end of outer needle **120** is positioned adjacent septum S. The pressure sensing element of inner needle **122** and/or of outer needle **120** may be used to determine that the distal tip of outer needle **120** is positioned adjacent septum S. FIG. **8**C also illustrates the reinforcement sleeve **123** being extended distally of elongate shaft **110**, either simultaneously with or independent of outer needle **120**, to reinforce the outer needle **120** and inner needle **122** during subsequent penetration of bodily tissue, such as through tough scar tissue of the septum S.

The snare device **402** and radiopaque distal tip of outer needle **120** and/or inner needle **122** may also be imaged via fluoroscope **20** to determine that the distal tip of outer needle **120** is near snare device **402**. As described herein, as the outer needle **120** curves or bends as it is being distally advanced, the inner needle **122** is also forced to curve or bend along with outer needle **120**. As shown in FIG. **8**D, when the outer needle **120** and inner needle **122** are positioned adjacent septum S, the second trigger mechanism **108** may be actuated so as to advance inner needle **122** distally of outer needle **120** and penetrate the septal wall S. The inner needle **122** is inserted through septum S and into right ventricle RV so that the distal end of inner needle **122** is disposed within snare **402**. As shown in FIG. **8**E, the guidewire GW is then inserted through a lumen of inner needle **122** and into right ventricle RV. The snare device **402** may then be retracted within catheter **404** so that the snare device **402** snares the distal tip of inner needle **122** and/or guidewire GW. With the distal tip of inner needle **122** snared

by snare device **402**, the inner needle **122** and outer needle **120** may be retracted within elongate shaft **110** so that the guidewire GW remains snared within snare device **402**.

The inner needle **122**, outer needle **120**, and elongate shaft **110** may then be removed from the patient's body and the guidewire GW may be pulled through catheter **404** or retracted through septum S and external wall EW to a position outside the patient's body. As shown in FIG. **8**F, in this manner, an insertion path of the guidewire GW and an insertion path of the catheter **404**/snare device **402** may be joined so that the guidewire GW, or another wire, extends from a first point outside the patient's body, through the external wall EW, through the septum S, through the jugular artery JA or femoral artery FA, and outside the patient's body at a second and different point. With guidewire GW extending through heart H and outside the patient's body as described above, a tension member or tether **412** may be coupled with the guidewire GW and inserted through the jugular artery JA, into the right ventricle RV, through septum S and external wall EW, and out of the patient's body. FIG. **8**F illustrates that the component inserted through heart H may represent the guidewire GW, the tension member **412**, or both.

A septal anchor (i.e., **410** of FIGS. **8**G-**8**I) is coupled with a distal end of tension member **412** so that as the tension member **412** is inserted through the jugular artery JA and through heart H, the septal anchor **410** is brought into position adjacent septum S. Exemplary embodiments of septal anchors **410** and tension members **412** are described in U.S. patent application Ser. No. 13/632,104, filed Sep. 30, 2012 and entitled "Trans-Catheter Ventricular Reconstruction Structures, Methods, and Systems for Treatment of Congestive Heart Failure and Other Conditions", the entire disclosure of which is incorporated herein by reference.

FIG. **8**G illustrates the septal anchor **410** positioned adjacent septum S within right ventricle RV. Tension member **412** extends from septal anchor **410** through septum S into left ventricle LV and through external wall EW. FIG. **8**H illustrates that an epicardial anchor **414** is coupled with tension member **412** and slid distally along tension member **412** until the epicardial anchor **414** is positioned adjacent external wall EW. An epicardial anchor application device **422** may be used to slide epicardial anchor **414** distally along tension member **412** to external wall EW. The epicardial anchor application device **422** may also be used to apply tension between septal anchor **410** and epicardial anchor **414** to urge or bring the septum S and external wall EW together. The epicardial anchor **414** may then be locked in place about tension member **412** to prevent the epicardial anchor **414** from moving about tension member **412** and to keep the septum S and external wall EW in position relative to one another. Exemplary embodiments of epicardial anchors **414** and epicardial anchor application devices **422** and uses thereof are described in U.S. patent application Ser. No. 13/632,104, which is incorporated by reference above.

As shown in FIG. **8**I, after the septal anchor **410** and epicardial anchor **414** are tensioned so that the septum S and external wall EW are brought together, the tension member **412** proximal to epicardial anchor **414** may be cut and discarded. The septal anchor **410** and epicardial anchor **414** may be left in position relative to septum S and external wall EW with the heart H reconfigured to reduce a volume of left ventricle LV and exclude scar tissue from the left ventricle LV. The above process may be repeated a plurality of times to position additional septal anchors **410** and/or epicardial anchors **414** about the septum S and external wall EW. The anchors may be aligned about a desired contour of the heart, such as a contour defined by scar tissue and the like. In some embodiments, the contour for placement of multiple anchors may be determined via an image of the heart and insertion points for the anchors may be calculated or measured from the image. The insertion points may then be mapped or marked on the heart, such as by using a template or pattern. In this manner, the shape of heart H and the volume of left ventricle LV may be reconfigured as desired.

In some embodiments, deployment of multiple anchors about the septum S and/or external wall EW may be accomplished using multiple access ports and trocars or shafts, or multiple anchors may be deployed via the same access port. For example, in some embodiments the tissue penetrating device may be used to penetrate the external wall EW and/or septum S in multiple locations via the same access port. The tissue penetrating device is capable of delivering multiple penetrations via a single access port due, in part, to the bending or curving of the outer and inner needle. Further, in some embodiments the tissue penetrating device may be inserted through various incisions to penetrate the heart's tissue and deliver heart anchors, such as through incisions between ribs, subxiphoid incisions, and the like. In one embodiment, the tissue penetrating device may be inserted through a subxiphoid incision to penetrate heart tissue (e.g., external wall EW and/or Septum S) closer to the heart's apex while being inserted through an incision between the ribs to penetrate heart tissue located away from the apex.

In another embodiment, the process illustrated in FIGS. **8**A-I may essentially occur in reverse. For example, the tissue penetrating device may be inserted into the arterial vasculature via the femoral artery FA and inferior vena cava IVC, via the jugular artery JA via the superior vena cava, or the like. In such embodiments, the elongate shaft **110** may be a catheter that is easily insertable and/or steerable through the patient's arteries and into the arterial vasculature. The catheter (i.e., elongate shaft **110**) may then be inserted into the right ventricle RV via the tricuspid valve and the distal tip of the catheter may be positioned adjacent the septum S. The inner needle **122** may then be advanced distally of the catheter to penetrate through the septum S. The outer needle **120** may then be advanced through the septum S and advanced toward the external wall EW. The outer needle **120** may bend, flex, or curve as it is being advanced toward the external wall EW as described herein.

A snare device **402** may be positioned adjacent the external wall EW and may provide a target for placement of the distal tip of the outer needle **120** relative to the external wall EW of the left ventricle LV. The distal tip of the outer needle **120** may be positioned adjacent the external wall EW at or near the target position defined by the snare device **402** and the inner needle **122** may be advanced distally of the outer needle **120**'s distal end to penetrate through the external wall EW. The inner needle **122**, and/or a guidewire GW inserted through the inner needle **122**'s lumen, may then be snared via snare device **402** so as to join a pathway of the guidewire GW and snare device **402** as described herein. Placement of the septal anchors and/or epicardial anchors may then be performed as described herein.

In some embodiments, the snare device **402** may be inserted through the external wall EW and into the left ventricle LV and the outer needle **120** may be advanced within the left ventricle LV toward the snare device **402**. The outer needle **122** may be advanced within the left ventricle LV until it is able to be snared by snare device **402**, after which the outer needle **120**, inner needle **122**, and/or guidewire GW may be snared to join access paths and deploy septal and/or epicardial anchors as described herein.

Although the tissue penetrating device is generally described herein as being used for treatment of congestive heart failure, it should be realized that the tissue penetrating device may be used for any procedure in which tissue is penetrated with a needle. For example, in some embodiments, the tissue penetrating device may be used in performing a biopsy of an organ or other tissue. The tissue penetrating device may allow a needle or coring device to be positioned around tissue within a patient in order to access tissue that is to be biopsied. Other applications of the tissue penetrating device are likewise possible.

Referring now to FIGS. **9**A-**9**E, illustrated is an embodiment of a tissue penetrating device **900** having a spring actuated triggering mechanism. FIGS. **9**B-**9**E illustrate enlarged cross section views of the device **900** showing the various components in greater detail. Tissue penetrating device **900** may be actuated to rapidly fire or deploy an outer needle and/or inner needle across the tissue of the patient, such as across an external wall EW or septal wall S. Device **900** includes a straight needle trigger rod **901** that may be actuated by a physician to rapidly deploy an inner and/or outer needle, and more commonly only an inner needle.

Device **900** includes an outer housing **902**. Device **900** further includes a trigger release sleeve **903** that may be rotated to release trigger release tabs **906** via a window **913** (FIG. **9**C) and thereby actuate trigger rod **901**. In one embodiment, device **900** may include 3 trigger release tabs **906** and 3 windows **913**. Device **900** additionally includes a trigger spring **904** that, upon actuation, causes trigger rod **901** to rapidly move distally relative to the other components of device **900**. Device **900** also includes a spring **905** for trigger release sleeve **903**. Device **900** additionally includes a straight or inner needle **907** that is rapidly fired or deployed upon actuation of trigger spring **904** and trigger rod **901**. Device **900** also includes a curved or outer needle **909** and two needle inserts **908** and **910**. An elongated shaft or sheath **911** is coupled with a distal end of insert **910** and includes a lumen within which outer needle **909** and inner needle **907** are coaxially aligned and slidably disposed. As shown in FIG. **9**C, the trigger release tabs **906** may be pivotally coupled to housing **902** via a pivot pin **912** and may prevent distal movement of trigger rod **901** until released by rotating trigger release sleeve **903** and aligning trigger release tabs **906** with corresponding windows **913**.

Rotating trigger release sleeve **903** so as to align trigger release tabs **906** with the corresponding windows **913** actuates trigger rod **901** and causes the trigger rod **901** to spring forward via trigger spring **904** until a distal end of trigger rod **901** contacts insert **908**. The forward springing movement of trigger rod **901** causes inner needle **907** to rapidly deploy relative to outer needle **909** and elongate shaft **911** and thereby penetrate tissue adjacent a distal end of the elongate shaft **911** and/or outer needle **909**. The trigger rod **901**, trigger spring **904**, and trigger release sleeve **903** may be reset for subsequent firing.

Having described several embodiments, it will be recognized by those of skill in the art that various modifications, alternative constructions, and equivalents may be used without departing from the spirit of the invention. Additionally, a number of well-known processes and elements have not been described in order to avoid unnecessarily obscuring the present invention. Accordingly, the above description should not be taken as limiting the scope of the invention.

Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limits of that range is also specifically disclosed. Each smaller range between any stated value or intervening value in a stated range and any other stated or intervening value in that stated range is encompassed. The upper and lower limits of these smaller ranges may independently be included or excluded in the range, and each range where either, neither or both limits are included in the smaller ranges is also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included.

As used herein and in the appended claims, the singular forms "a", "an", and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a process" includes a plurality of such processes and reference to "the device" includes reference to one or more devices and equivalents thereof known to those skilled in the art, and so forth.

Also, the words "comprise," "comprising," "include," "including," and "includes" when used in this specification and in the following claims are intended to specify the presence of stated features, integers, components, or steps, but they do not preclude the presence or addition of one or more other features, integers, components, steps, acts, or groups.

What is claimed is:

1. A method of penetrating tissue of a patient with a tissue penetrating device having a first needle and a second needle disposed within a lumen of the first needle, the method comprising:

advancing the first needle towards a first tissue surface of the patient to position a distal tip of the first needle adjacent to the first tissue surface;

extending the second needle distally of the first needle's distal tip to penetrate the first tissue surface with the second needle, the second needle being coaxially aligned with a distal end of the first needle as the second needle is extended distally of the first needle's distal tip and through the first tissue surface;

advancing the first needle over the second needle and through the first tissue surface so that the second needle is disposed within the first needle's lumen and so that the second needle's distal tip is positioned distally of the first tissue surface;

advancing the first needle distally of the first tissue surface and towards a second tissue surface of the patient to position the first needle's distal tip adjacent to the second tissue surface, wherein the first needle bends or curves from a first orientation to a second orientation as the first needle is advanced towards the second tissue surface; and

extending the second needle distally of the first needle's distal tip to penetrate the second tissue surface with the second needle, the second needle being coaxially aligned with the distal end of the first needle as the second needle is extended distally of the first needle's distal tip and through the second tissue surface.

2. The method of claim **1**, wherein the first needle is made of a flexible shape-memory material having a preconfigured bend or curve such that advancing the first needle distally of the first tissue surface effects an automatic bending or curving of the first needle from the first orientation to the second orientation.

3. The method of claim **1**, wherein advancing the first needle comprises actuating a first trigger mechanism of the tissue penetrating device.

4. The method of claim 3, wherein extending the second needle comprises actuating a second trigger mechanism of the tissue penetrating device, the second trigger mechanism being operable independent of the first trigger mechanism.

5. The method of claim 4, wherein actuating the first trigger mechanism or the second trigger mechanism comprises actuating a spring mechanism that causes the first needle or the second needle to rapidly deploy.

6. The method of claim 1, wherein the method further comprises inserting a guidewire through a lumen of the second needle subsequent to penetrating the first tissue surface or the second tissue surface.

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